EPA Jacket 1706-240
Vol.1

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: 12/23/10		EPA Reg. Number: 1706-EUN		
	Check List Item	Yes	No	N/A
1	Has the **PRIA Fee been Paid**; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an **Application Form** (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a **Confidential Statement of Formula** (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a **Formulator's Exemption Statement** (EPA Form 8570-27) Included in the Submission Package?		X	
5	Is a **Certification with Respect to Citation of Data** (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a **Data Matrix** (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a **Label** Included in the Submission Package?	X		
8	Are **Data** Included in the Submission Package?	X		
9	**Is the Submission an Amendment?**		X	

Re [redacted]

Philip Ross
to:
Dennis Edwards
03/03/2011 09:46 AM
Cc:
Chris Kaczmarek, Joan Harrigan-Farrelly, Tracy Lantz
Hide Details
From: Philip Ross/DC/USEPA/US

To: Dennis Edwards/DC/USEPA/US@EPA

Cc: Chris Kaczmarek/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA

Security:

To ensure privacy, images from remote sites were prevented from downloading. Show Images

Attorney Client Communication
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[redacted]al information may be entitled to confidential treatment*

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

-----Dennis Edwards/DC/USEPA/US wrote: -----

Internal deliberative, *Privileged attorney-client communication*, *Attorney work product*

To: Philip Ross/DC/USEPA/US@EPA
From: Dennis Edwards/DC/USEPA/US
Date: 03/02/2011 05:50PM
Cc: Chris Kaczmarek/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA
Subject: Re: [redacted]

Phil

[redacted]

Dennis

Dennis Edwards, Chief
Regulatory Management Branch 1
Antimicrobials Division
703-308-8087

Philip Ross---03/02/2011 12:55:24 PM---Attorney Client Communication Attorney Work Product

From: Philip Ross/DC/USEPA/US
To: Dennis Edwards/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA
Cc: Chris Kaczmarek/DC/USEPA/US@EPA
Date: 03/02/2011 12:55 PM
Subject: [redacted]

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[redacted]

Phil

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

Internal deliberative, *Privileged attorney-client communication*, *Attorney work product*

Re: [redacted]

Dennis Edwards to: Philip Ross 03/02/2011 05:50 PM
Cc: Chris Kaczmarek, Joan Harrigan-Farrelly, Tracy Lantz

Phil

[redacted]

Dennis

Dennis Edwards, Chief
Regulatory Management Branch 1
Antimicrobials Division
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Date: 03/02/2011 12:55 PM
Subject: [redacted]

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[redacted]

Phil

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

RE: 1706-EUN chem review 2/17 Ammonium sulfate

Mann, Juliana to: Tracy Lantz 03/02/2011 03:02 PM

Cc: Velma Noble, Dennis Edwards

Hi Tracy,

The email was received and we will have a response to you by 3/14.

Thanks,
Juli

Juli Mann | Paralegal Specialist | Steptoe & Johnson LLP |1330 Connecticut Avenue, NW | Washington, DC 20036-1795 | Phone: 202-429-3095 | Fax: 202-429-3902 | jmann@steptoe.com

-----Original Message-----
From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov]
Sent: Wednesday, March 02, 2011 2:42 PM
To: Mann, Juliana
Cc: Noble.Velma@epamail.epa.gov; Edwards.Dennis@epamail.epa.gov
Subject: Fw: 1706-EUN chem review 2/17 Ammonium sulfate

Please confirm that you received this message and will reply by 3/14.
(Embedded image moved to file: pic15120.jpg)

----- Forwarded by Tracy Lantz/DC/USEPA/US on 03/02/2011 02:41 PM -----

From: Tracy Lantz/DC/USEPA/US
To: "Mann, Juliana" <JMann@steptoe.com>
Cc: Velma Noble/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA
Date: 02/28/2011 07:39 AM
Subject: Fw: 1706-EUN chem review 2/17 Ammonium sulfate

Dear Juli,

Please see the attached product chemistry review for 1706-EUN.
Address the concerns identified by our chemist: chemical incompatibility and information regarding leak/spill cleanup need to be addressed via the product label.

Please provide this information by 3/14 via pdf. If you will be unable to provide this information by this date, please contact me as soon as possible.

Thanks
(Embedded image moved to file: pic23917.jpg)

----- Forwarded by Tracy Lantz/DC/USEPA/US on 02/27/2011 11:06 PM -----

From: cts/cts/QP/USEPA/US@EPA
To: Tracy Lantz/DC/USEPA/US@EPA

Date: 02/24/2011 06:12 PM
Subject: 1706-EUN chem review 2/17 Ammonium sulfate

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device.(See attached file: [Untitled].pdf)

Fw: 1706-EUN chem review 2/17 Ammonium sulfate
Tracy Lantz to: Mann, Juliana 03/02/2011 02:42 PM
Cc: Velma Noble, Dennis Edwards

Please confirm that you received this message and will reply by 3/14.

Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

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Internal deliberative

Nancy Steven Melba
Earl Dennis
Ian Nader Karen
Steve Tim Velma

David Boyd not present

3/1/11

[redacted]

Internal deliberative

Najm
Melba
Joan
Dennis

Tracy
Brenda OECA
Phil OGC
Chris OGC
2/16/11

Response to Ashland on Nalco applications

[redacted]

Internal deliberative

Internal deliberative

2/8/11
Sent data package for Ian for 1706-EGO + 1706-EUR to Ian
2/8/11

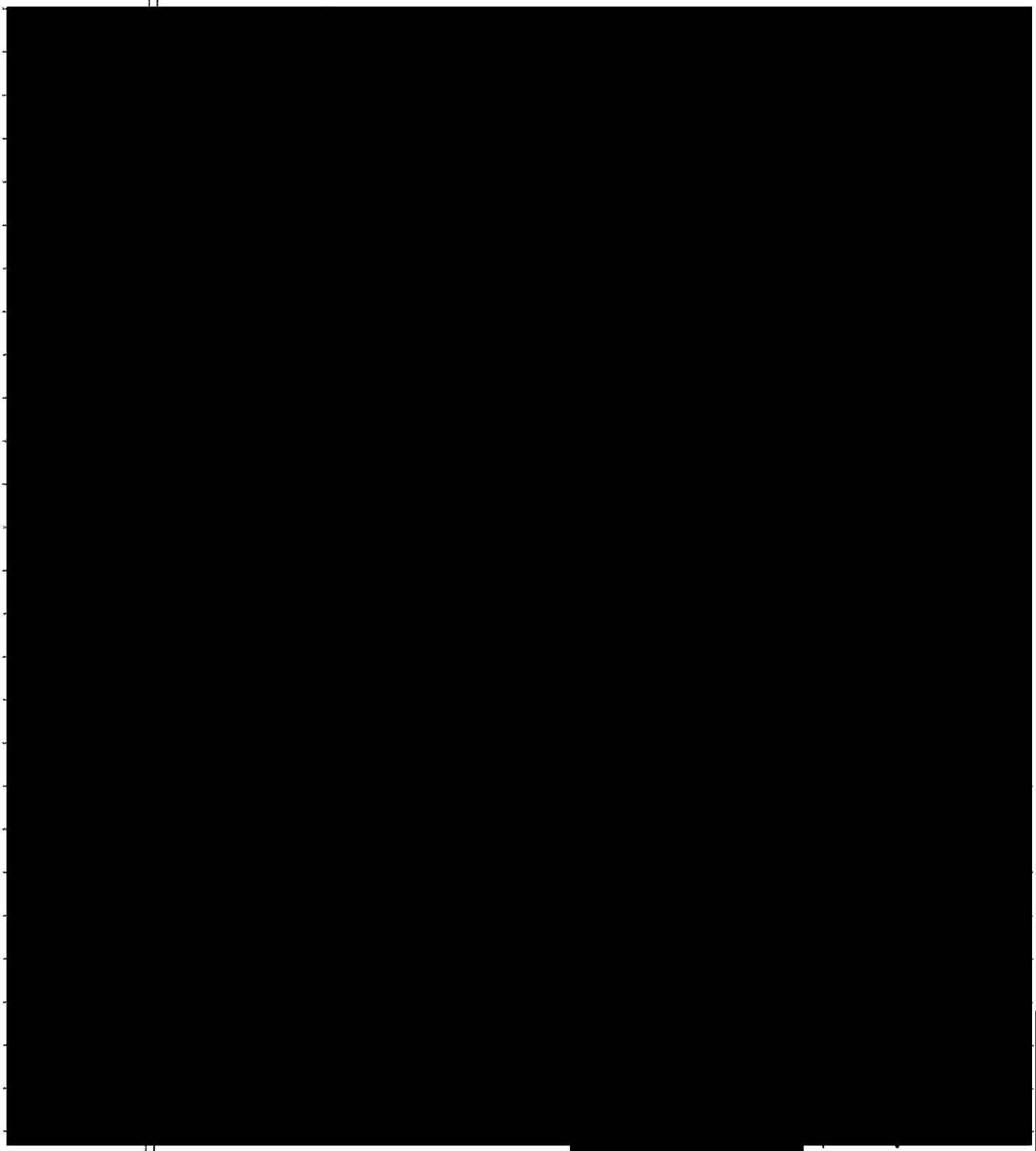
...monium Sulfate +
Urea
new AI's

[redacted]

Steve M.
Bill H.
Sreeni
David B.
Ian B.
Nathan M.
Tim O.
Najm
Dennis
Nader

[redacted]

[redacted]



2/1/11

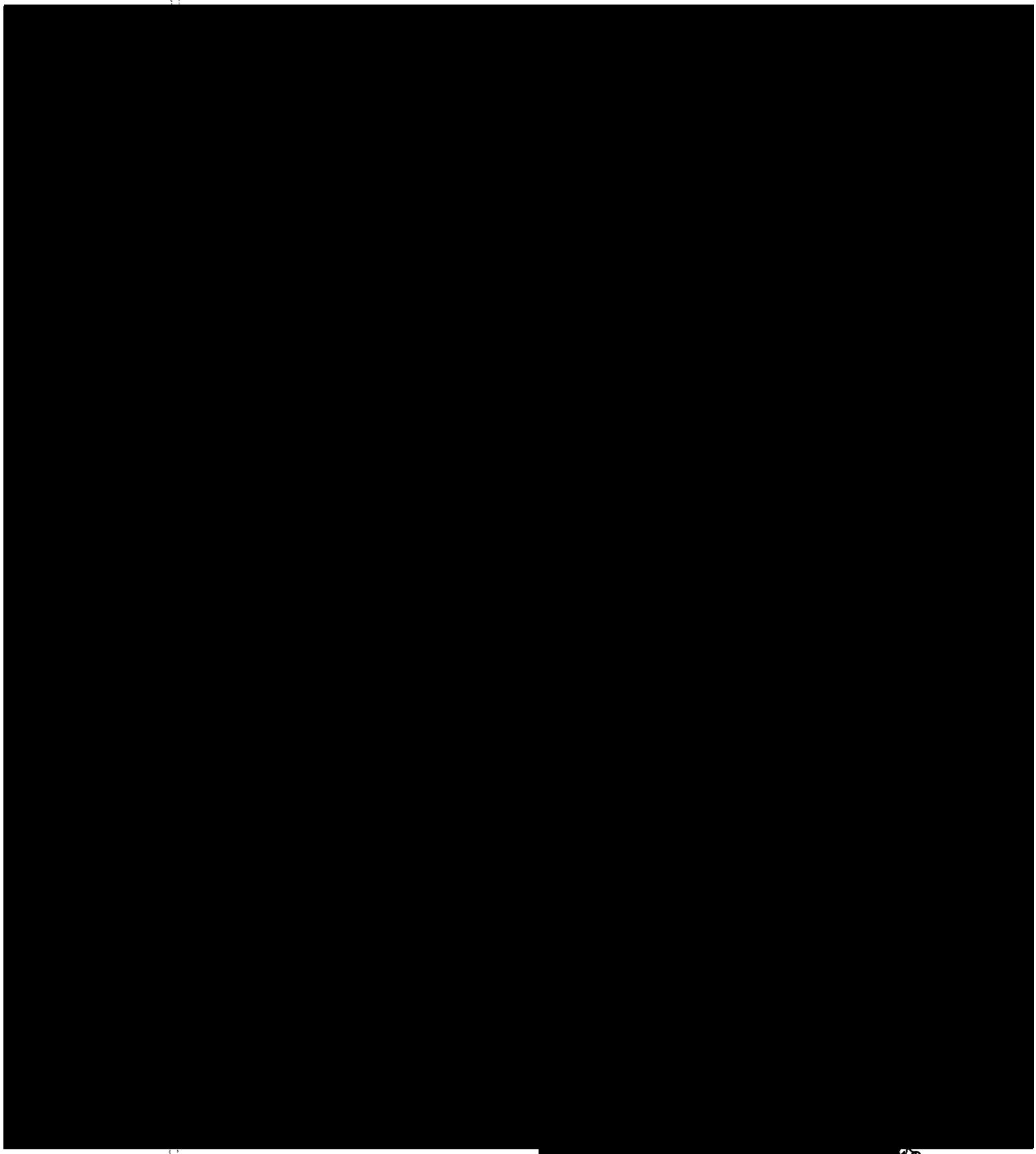
Internal Scoping Mtg on Nalco new AI's:
Ammonium Sulfate + Urea

In person:		by conf. call:
Tim M.	David B.	Tracy ✓
Steve M.	Najm	Ian ✓
Nader E.	(is Nathan there? yes)	Velma ✓
Melba M.		Karen H. ~~✗~~ on-the line, too
Earl		
Dennis		

Internal deliberative

[redacted]

Internal deliberative



[redacted]

Internal deliberative

[redacted] Dennis Edwards to: Velma Noble, Melba Morrow, Tracy Lantz 02/28/2011 07:41 PM

----- Forwarded by Dennis Edwards/DC/USEPA/US on 02/28/2011 07:40 PM -----

From: Philip Ross/DC/USEPA/US
To: Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Leslye Fraser/DC/USEPA/US@EPA
Cc: Bill Diamond/DC/USEPA/US@EPA, Brenda Mosley/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, Don Lott/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, John Ruggero/DC/USEPA/US@EPA, Kim Wilson/DC/USEPA/US@EPA, Rosemarie Kelley/DC/USEPA/US@EPA, Steven Bradbury/DC/USEPA/US@EPA
Date: 02/28/2011 05:20 PM
Subject: [redacted]

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Joan--

[redacted]

Phil

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

Joan Harrigan-Farrelly [redacted] 02/28/2011 05:10:39 PM

From: Joan Harrigan-Farrelly/DC/USEPA/US
To: Philip Ross/DC/USEPA/US@EPA, Steven Bradbury/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA
Cc: Kim Wilson/DC/USEPA/US@EPA, Brenda Mosley/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA, Don Lott/DC/USEPA/US@EPA, John Ruggero/DC/USEPA/US@EPA, Rosemarie Kelley/DC/USEPA/US@EPA, Bill Diamond/DC/USEPA/US
Date: 02/28/2011 05:10 PM
Subject: [redacted]

Internal deliberative, *Privileged attorney-client communication*, *Attorney work product*

[redacted]

Joan
Joan

Sent by EPA Wireless E-Mail Services

Philip Ross

----- Original Message -----
From: Philip Ross
Sent: 02/28/2011 04:52 PM EST
To: Steven Bradbury; Joan Harrigan-Farrelly; Jennifer Mclain; Dennis Edwards
Cc: Kim Wilson; Brenda Mosley; Chris Kaczmarek; Don Lott; John Ruggero; Philip Ross; Rosemarie Kelley
Subject: [redacted]

Attorney Client Communication
Attorney Work Product
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Privileged and Confidential
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Steve, Joan, Jennifer, and Dennis:

[redacted]

Phil

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

----- Forwarded by Philip Ross/DC/USEPA/US on 02/28/2011 04:41 PM -----

From:	Kim Wilson/DC/USEPA/US
To:	Kim Wilson/DC/USEPA/US@EPA
Cc:	Brenda Mosley/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA, Don Lott/DC/USEPA/US@EPA, John Ruggero/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA, Rosemarie Kelley/DC/USEPA/US@EPA
Date:	02/28/2011 04:35 PM
Subject:	[redacted]

Internal deliberative, *Privileged attorney-client communication*, *Attorney work product*

[redacted]

Kimberly Wilson, Attorney-Advisor
U.S. Environmental Protection Agency, Office of Civil Enforcement
Waste and Chemical Enforcement Division, Pesticides and Tanks Enforcement Branch
phone: 202-564-5607, fax: 202-564-0022

Kim Wilson [redacted] 02/28/2011 04:29:29 PM

From: Kim Wilson/DC/USEPA/US
To: Philip Ross/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA
Cc: Rosemarie Kelley/DC/USEPA/US@EPA, Don Lott/DC/USEPA/US@EPA, John Ruggero/DC/USEPA/US@EPA, Brenda Mosley/DC/USEPA/US@EPA
Date: 02/28/2011 04:29 PM
Subject: [redacted]

Phil and Chris,

[redacted]

Speak to you soon,

Kimberly Wilson, Attorney-Advisor
U.S. Environmental Protection Agency, Office of Civil Enforcement
Waste and Chemical Enforcement Division, Pesticides and Tanks Enforcement Branch
phone: 202-564-5607, fax: 202-564-0022

Fw: 1706-EUN chem review 2/17 Ammonium sulfate
Tracy Lantz to: Mann, Juliana 02/28/2011 07:39 AM
Cc: Velma Noble, Dennis Edwards

Dear Juli,

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U. S. Environmental Protection Agency
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Date: 02/24/2011 06:12 PM
Subject: 1706-EUN chem review 2/17 Ammonium sulfate

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

February 17, 2011

DP BARCODE: 385697

MRID : 483408-01 thru 483408-04

SUBJECT: Naico 60620
(Name of Product)

File Symbol.: 1706-EUN

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [x]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
005601	7783-20-2	Ammonium sulfate

TEST LAB(s): Case Consulting Laboratories, Inc.
SBC Laboratories, Inc.

SUBMITTER: Naico Company

GUIDELINE: Product Chemistry Group A and B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVER: Karen P. Hicks

APPROVED DATE: February 17, 2011

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

February 17, 2011

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA File Symbol: 1706-EUN
Product Name: Nalco 60620
DP Barcode: 385697

CODE: (A380) New AI, Food Use, With Exemption,
No Fee: Linked to PRIA Application

DATE DUE: April 16, 2011

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Velma Noble PM#31/Tracy Lantz
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Nalco Company

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Ammonium sulfate	20.0
Other Ingredient(s):	80.0
Total:	100.0

BACKGROUND:

On behalf of Nalco Company, Steptoe & Johnson, LLP has submitted an application for registration of a new end-use product, Nalco 60620. The product is produced by an integrated formulation system (i.e., the product contains an active ingredient that is not an EPA-registered product). This product is to be used in conjunction with a solution of sodium hypochlorite to produce a stabilized chlorine solution within their OxiPro® delivery system. The resulting active ingredient created is for use in controlling bacteria, algae, and fungi in pulp and paper mill water systems.

The data package included the following documents dated December 23, 2010:

1. Letter from the applicant's representative to EPA.
2. EPA Form 8570-1 (Application for Pesticide).
3. Confidential Statement of Formula (CSF) for the basic formulation, dated December 23, 2010.
4. EPA Form 8570-35 (Data Matrix).
5. Draft label
6. Five study documents (MRID 483408-01 through 483408-04).
7. Revised draft label dated February 11, 2011

Note: The data package also included a document prepared by McKenna Long & Aldridge LLP, regarding the registration of certain ammonia products. CTT believes this was provided as regulatory background material which is not considered as subject to product chemistry review.

FINDINGS: A detailed review breakdown may be found in Product Chemistry Review I, II and in Table A and B starting on page 4. Items listed here provide additional comments and items which must be addressed.

1. Confidential Statement of Formula: The basic CSF dated September 23, 2010 is acceptable.

2. Product Label: Labeling recommendations.

    a. Under the new "Physical or Chemical Hazards" section of the product label, place a statement regarding the incompatibility of the product with other chemicals (e.g., strong oxidizers, acids, bases, nitrates, and hypochlorites).
    b. Add the heading "Physical or Chemical Hazards" immediately beneath the "Environmental Hazards" section of the product label.
    c. Under the "Pesticide Storage" section of the product label, add instructions that specify what to do if the product leaks or spills from the product container.

3. Product Chemistry Group A and B

    a. Product Chemistry Group A. OPPTS 830.1750 (Certified Limits) a signed certification statement must be provided, as requested under OPPTS 830.1750(g).

    b. Product Chemistry Group B

        i. OPPTS 830.6314 (Oxidation/Reduction: Chemical Incompatibility) study is waived based upon known chemical incompatibilities of urea with other chemicals. Chemical incompatibilities must be listed on the product label. See Product Label FINDINGS #2 a. (above)
        ii. OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) study. The agent for the registrant reports that this study is in process and will be reported to the Agency upon completion.

CONCLUSION:

The basic CSF dated December 23, 2011 is found to be acceptable as submitted. Several labeling revisions are recommended. Additionally, issues have been identified in both product chemistry group A and group B.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system Yes [ ] No [X]
- Are all TGAIs used registered? Yes [ ] No [X]
- Integrated formulation system Yes [X] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.

Yes [ ] No [ ]

Note: The product consists of [redacted]*. Not intended for food use.*

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [X]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC (%)	LCL (%)	UCL (%)
Ammonium sulfate	20.00	19.0	21.0

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

Inert ingredient information may be entitled to confidential treatment

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X]No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statements regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [X] No]]

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	483408-01 and CSF
830.1600 Description of Materials	A	483408-01
830.1620 Production Process[2]	NA –	
830.1650 Formulation Process[3]	A	483408-01 and CSF
830.1670 Formation of Impurities[4]	A	483408-01
830.1700 Preliminary Analysis[5]	A – Results from the analysis of five batches of the pure active ingredient were provided. Testing was conducted in compliance with GLP.	483408-02
830.1750 Certified Limits[6]	A – Standard certified limits were proposed. G – A signed certification statement must be provided, as requested under OPPTS 830.1750(g).	483408-01 and CSF
830.1800 Enforcement Analytical Method[7]	A – A copy of a titration method was provided for determining active ingredient content in the product.	483408-01
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The color of the product is clear, based on visual inspection.	483408-03
830.6303 Physical State	A	The product is a liquid, based on visual inspection.	483408-03
830.6304 Odor	A	The product is odorless, based on observation.	483408-03
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	Not applicable. The product is not intended to be in contact with metal or metal ions in storage or to be stored at elevated temperatures.	483408-03
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	A wavier is requested based on the well-known reactivity of ammonium sulfate. Note: The MSDS for ammonium sulfate indicates incompatibility with strong oxidizers, bases, chlorates, and nitrates.	483408-03
830.6315 Flammability/ Flame Extension	NA	Not applicable. The product does not contain combustible liquids.	483408-03
830.6316 Explodability	NA	Not applicable. The product is not potentially explosive.	483408-03
830.6317 Storage Stability	G	A storage stability study is currently underway. Results will be provided to EPA once the study is complete.	Agent's Letter
830.6319 Miscibility[1]	NA	Not applicable. The product is not an emulsifiable liquid or diluted with petroleum solvents.	483408-03
830.6320 Corrosion Characteristics	G	A corrosion characteristics study is currently underway. Results will be provided to EPA once the study is complete.	Agent's Letter
830.6321 Dielectric Breakdown Voltage	NA	Not applicable. The product is not intended for use around electrical equipment.	483408-03

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7000 pH[2]	A	The mean pH of the product was reported to be 5.52 at 25.1°C. A 1% w/w solution of the product in CO_2-free reagent water was tested. Three determinations were made. Testing was conducted in compliance with GLP.	483408-04
830.7050 UV/Visible Absorption	NA	*[Not required for end-use products.]*	
830.7100 Viscosity	A	The mean viscosity of the product was reported to be 1.25 cP at 20.0°C (at 30 rpm) and 0.70 cP at 40.0°C (at 30 rpm) (as determined using a Brookfield rotational viscometer). Two determinations were made at each temperature. Measurements were also made at 60 rpm. Testing was conducted in compliance with GLP.	483408-04
830.7200 Melting Point/Melting Range	NA	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	The mean density of the product was reported to be 1.0563 g/mL at 20.0°C. Three determinations were made. Testing was conducted in compliance with GLP.	483408-04
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

Re: [redacted]
Dennis Edwards to: Najm Shamim 02/18/2011 09:21 AM
Cc: Nader Elkassabany, Tracy Lantz, William Hazel

Hi Najm

[redacted]

Dennis

Dennis Edwards, Chief
Regulatory Management Branch 1
Antimicrobials Division
703-308-8087

Najm Shamim [redacted] 02/18/2011 08:13:23 AM

From: Najm Shamim/DC/USEPA/US
To: Dennis Edwards/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, William Hazel/DC/USEPA/US@EPA
Cc: Nader Elkassabany/DC/USEPA/US@EPA
Date: 02/18/2011 08:13 AM
Subject: [redacted]

[redacted]

Najm

Re: [redacted]
Philip Ross
to:
Joan Harrigan-Farrelly, Chris Kaczmarek
02/15/2011 10:05 AM
Cc:
Caroline Klos, Dennis Edwards, Jennifer Mclain, Melba Morrow, Najm Shamim, Tracy Lantz
Hide Details
From: Philip Ross/DC/USEPA/US Sort List...

To: Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA

Cc: Caroline Klos/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, Melba Morrow/DC/USEPA/US@EPA, Najm Shamim/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA

Security:

To ensure privacy, images from remote sites were prevented from downloading. Show Images

Attorney Client Communication
Attorney Work Product
Deliberative
Privileged and Confidential
Do Not Release

[redacted]

Internal deliberative, *Privileged attorney-client communication*, *Attorney work product*

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

-----Joan Harrigan-Farrelly/DC/USEPA/US wrote: -----

To: Melba Morrow/DC/USEPA/US@EPA
From: Joan Harrigan-Farrelly/DC/USEPA/US
Date: 02/15/2011 08:49AM
Cc: Caroline Klos/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, Najm Shamim/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA
Subject: Re: [redacted]

[redacted]

Joan

Melba Morrow---02/14/2011 07:14:00 PM---[redacted]. Melba S. Morrow, D.V.M. Special Assistant , RMB1

From: Melba Morrow/DC/USEPA/US
To: Joan Harrigan-Farrelly/DC/USEPA/US@EPA
Cc: Caroline Klos/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, Najm Shamim/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA
Date: 02/14/2011 07:14 PM
Subject: Re: [redacted]

[redacted]

Internal deliberative

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-308-2716
703-308-8481 (fax)

Joan Harrigan-Farrelly---02/14/2011 06:16:57 PM---[redacted]

From: Joan Harrigan-Farrelly/DC/USEPA/US
To: Dennis Edwards/DC/USEPA/US@EPA, Melba Morrow/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Najm Shamim/DC/USEPA/US@EPA, Caroline Klos/DC/USEPA/US@EPA
Cc: Philip Ross/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA
Date: 02/14/2011 06:16 PM
Subject: [redacted]

[redacted]

Internal deliberative

[redacted]

Joan

Internal deliberative

Re: [redacted]

Melba Morrow to: Joan Harrigan-Farrelly 02/14/2011 07:14 PM

Cc: Caroline Klos, Dennis Edwards, Najm Shamim, Tracy Lantz, Jennifer Mclain

History: This message has been replied to.

[redacted]

Melba S. Morrow, D.V.M.
Special Assistant , RMB1
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-308-2716
703-308-8481 (fax)

Joan Harrigan-Farrelly [redacted] 02/14/2011 06:16:57 PM

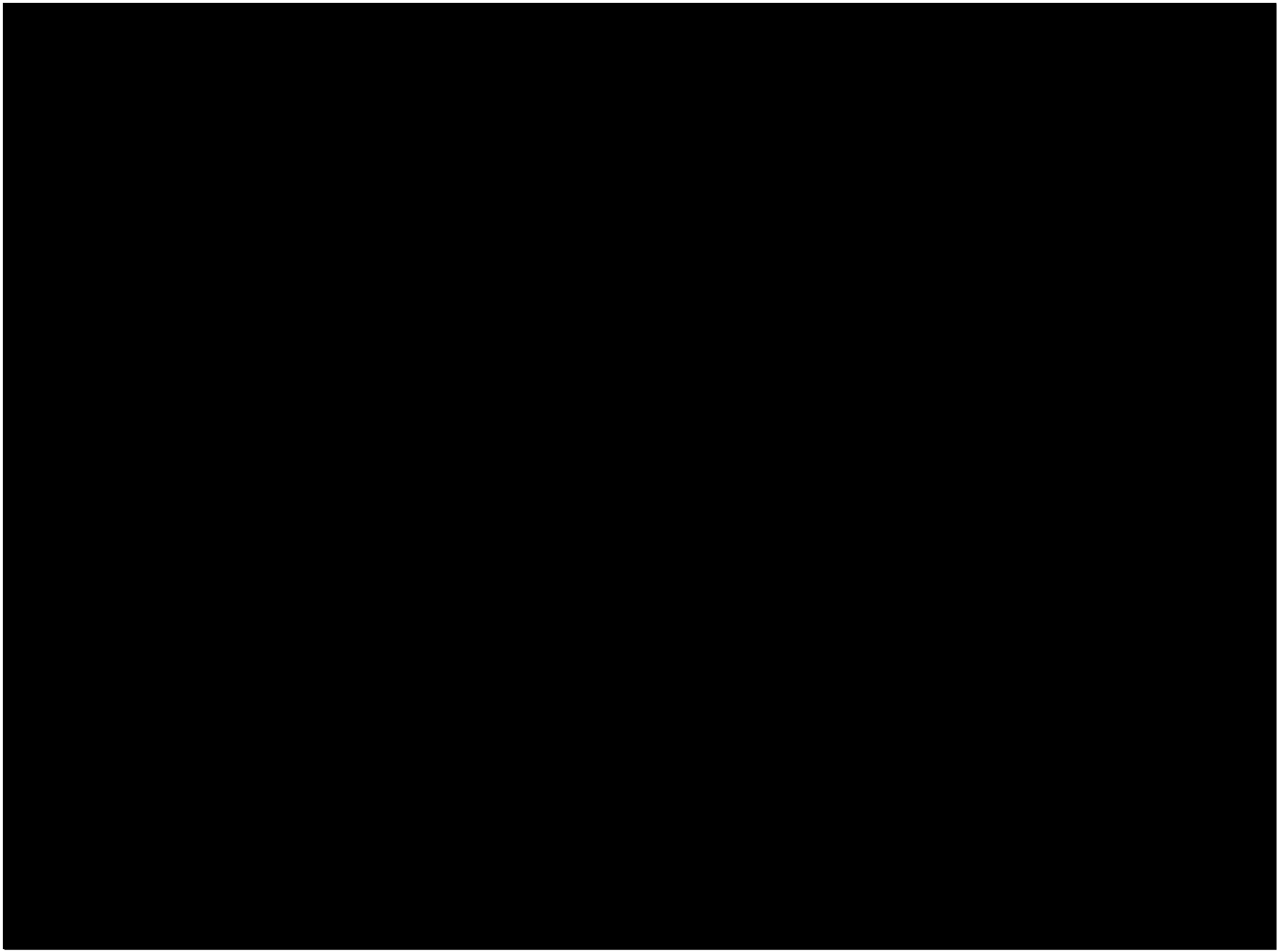
From: Joan Harrigan-Farrelly/DC/USEPA/US
To: Dennis Edwards/DC/USEPA/US@EPA, Melba Morrow/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Najm Shamim/DC/USEPA/US@EPA, Caroline Klos/DC/USEPA/US@EPA
Cc: Philip Ross/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA
Date: 02/14/2011 06:16 PM
Subject: [redacted]

Internal deliberative

[redacted]

Joan

Internal deliberative



Re: [redacted]

Joan Harrigan-Farrelly to: Melba Morrow 02/11/2011 10:27 PM

Cc: Dennis Edwards, Glen McLeod, Najm Shamim, Tracy Lantz, Jennifer Mclain

Melba, All,

[redacted]

Internal deliberative

Joan

Joan Harrigan Farrelly
US Environmental Protection Agency
Director, Antimicrobials Division
Office of Pesticide Programs
1200 Pennsylvania Ave. N.W. Mailcode 7510P
Washington, DC 20460

Physical Address
One Potomac Yard
2777 Crystal Dr.
Arlington, VA 22202
Phone: 703-603-8914

Melba Morrow [redacted] 02/11/2011 11:19:47 AM

From: Melba Morrow/DC/USEPA/US
To: Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Najm Shamim/DC/USEPA/US@EPA, Glen McLeod/DC/USEPA/US@EPA
Date: 02/11/2011 1 t:19 AM
Subject: [redacted]

[redacted]

Melba S. Morrow, D.V.M.
Special Assistant , RMB1
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-308-2716
703-308-8481 (fax)

Internal deliberative

[redacted]

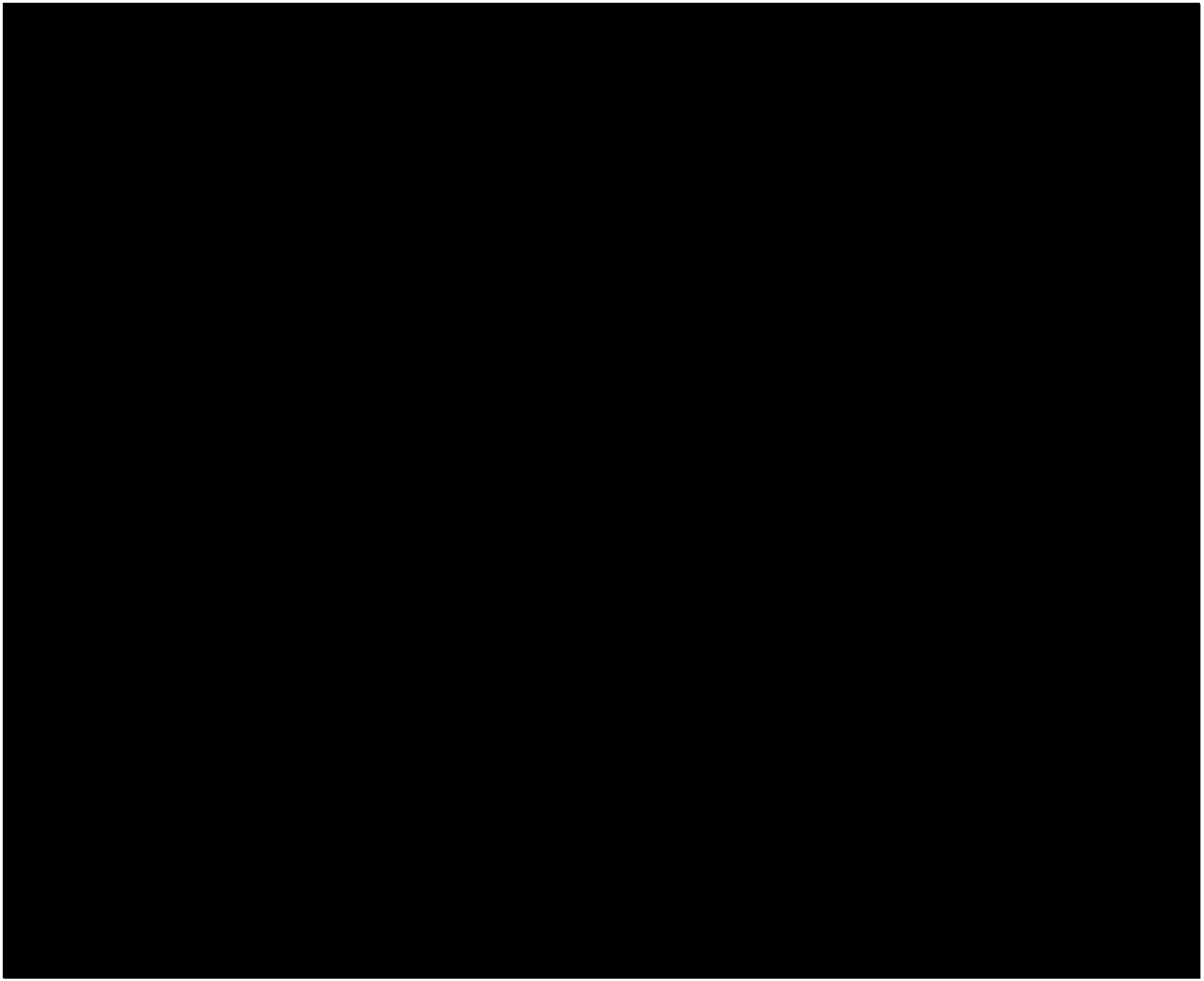
Melba Morrow to: Joan Harrigan-Farrelly, Dennis Edwards, Tracy Lantz, Najm Shamim, Glen McLeod 02/11/2011 11:19 AM

History: This message has been replied to.

[redacted]

Melba S. Morrow, D.V.M.
Special Assistant , RMB1
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-308-2716
703-308-8481 (fax)

Internal deliberative



Fw: [redacted]

Dennis Edwards to: Velma Noble 02/11/2011 09:11 AM
Cc: Melba Morrow, Tracy Lantz

Hi Velma

[redacted]

Dennis

Dennis Edwards, Chief
Regulatory Management Branch 1
Antimicrobials Division
703-308-8087
----- Forwarded by Dennis Edwards/DC/USEPA/US on 02/11/2011 09:06 AM -----

From: Joan Harrigan-Farrelly/DC/USEPA/US
To: "Dennis Edwards" <Edwards.Dennis@epa.gov>, "Melba Morrow" <Morrow.Melba@epamail.epa.gov>, "Tracy Lantz" <Lantz.Tracy@epamail.epa.gov>
Date: 02/11/2011 07:50 AM
Subject: [redacted]

Sent by EPA Wireless E-Mail Services

Internal deliberative

Revised 1706-EGO, -EUR, -EUN labels
Mann, Juliana
to:
Tracy Lantz
02/11/2011 12:49 PM
Cc:
Dennis Edwards
Hide Details
From: "Mann, Juliana" <JMann@steptoe.com>

To: Tracy Lantz/DC/USEPA/US@EPA

Cc: Dennis Edwards/DC/USEPA/US@EPA

Paid

History: This message has been replied to and forwarded.

3 Attachments

1706-EUN.Nalco60620label.pdf 1706-EUR.Nalco60630label.pdf 1706-EGO.Nalco60615label.pdf

Tracy:

The revised labels are attached. I will send the data matrix forms to you shortly.

Thank you,

Juli

requested A420

Juli Mann | Paralegal Specialist | Steptoe & Johnson LLP |1330 Connecticut Avenue, NW | Washington, DC 20036-1795 | Phone: 202-429-3095 | Fax: 202-429-3902 | jmann@steptoe.com

Revised 1706-EGO, -EUR, -EUN labels
Mann, Juliana
to:
Tracy Lantz
02/11/2011 12:49 PM
Cc:
Dennis Edwards
Show Details

Tracy:

The revised labels are attached. I will send the data matrix forms to you shortly.

Thank you,

Juli

Juli Mann | Paralegal Specialist | Steptoe & Johnson LLP |1330 Connecticut Avenue, NW | Washington, DC 20036-1795 | Phone: 202-429-3095 | Fax: 202-429-3902 | jmann@steptoe.com

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May cause irritation to the eyes, and skin. Do not get in eyes, on skin, or on clothing. Do not take internally. Use with adequate ventilation Rinse thoroughly with water after handling. Remove contaminated clothing and wash clothing before reuse. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves (rubber, chemical resistant) when handling.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

(Container Handling statements not applicable to bulk containers)

(Instructions for refillable containers:)

CONTAINER HANDLING: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedure approved by state and local authorities.

(Instructions for non-refillable containers greater than 5 gallons:)

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Triple rinse (or equivalent) container promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedure approved by state and local authorities.

NALCO

Nalco 60620

A MICROORGANISM CONTROL CHEMICAL

ACTIVE INGREDIENT:	
Ammonium Sulfate	20.0%
INERT INGREDIENTS	80.0%
TOTAL	100.0%

EPA Reg. No. 1706-XXX

EPA Est. No. 1706-))-1 (BP) EPA Est. No. 1706-WA-1 (VW)
EPA Est. No. 1706-PA-1 (EL) EPA Est. No. 1706-LA-2 (PL)
Letter in () that matches first letter in batch number identifies the establishment number

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

- IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
- IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told by a poison control center or doctor. Do not give anything to an unconscious person.
- IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
- IF INHALED: Move person to fresh air. If person is not breathing, call 911 or ambulances, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice

NOTE: Have the product container or label with you when calling a poison control center or a doctor, or going for treatment.

SEE LEFT SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Nalco Company
1601 West Diehl Road
Naperville, IL 60563-1198
EMERGENCY PHONE NO. (800) 424-9300

1706-EUN

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For the control bacteria, algae and fungi. Nalco 60620 is used in conjunction with: 1) sodium hypochlorite (typically 12.5%) to produce stabilized chlorine as chloramine; and 2) the OxiPRO delivery system as described below

Nalco 60620 and the sodium hypochlorite are mixed in a specially designed system that produces the stabilized chlorine solution on site. The products are blended to achieve a minimum molar ratio of 1.0-1.2 to 1.0 Nalco 60620 to sodium hypochlorite (12.5%). The stabilized chlorine is typically achieved by mixing 1.5 gallons of Nalco 60620 with 1.0 gallon of sodium hypochlorite (12.5%). The OxiPRO delivery system controller ensures the automatic production of the dilute stabilized chlorine solution, controls the optimization of the production process, and ensures adequate dosing into the water system requiring treatment. The design, treatment, installation, calibration, and operation of the feeding system in all plants should be conducted only by authorize and trained personnel.

Use of this product for any other purposes or contrary to the instructions below, or without the supervision of authorized trained personnel is prohibited.

Note: Do not use other feeding modes to mix Nalco 60620 and the sodium hypochlorite. Non-authorized personnel are prohibited from operating or otherwise handling the feeding system or its chemical ingredients.

PULP AND PAPERMILL WATER SYSTEMS

Dosage Rates: When the system is noticeably fouled, apply sufficient Nalco 60620 and sodium hypochlorite to achieve a chlorine residual in excess of the system oxidant demand. The stabilized chlorine solution produced by the delivery system is immediately added to the process waters for which treatment is required. The stabilized chlorine solution may be added to any point of uniform mixing. Addition may be continuous or intermittent depending on the severity of the contamination when treatment starts, and on other system operation parameters.

A. SLUG FEED METHOD

Initial Dose: When the system is noticeably fouled, add the appropriate amount of stabilized chlorine to the system to obtain from 1 to 10 ppm total available chlorine. The recommended stabilized chlorine is typically achieved by mixing 1.5 gallons of Nalco 60620 with 1.0 gallon of sodium hypochlorite (12.5%). Repeat until control is achieved. Badly fouled systems must be cleaned before treatment is begun.

Subsequent Dose: When microbial control is evident, add the appropriate amount of stabilized chlorine to the system daily, or as needed to maintain control and keep the total chlorine residual at 1 to 10 ppm.

B. INTERMITTENT FEED METHOD

Initial Dose: When the system is noticeably fouled, add the appropriate amount of stabilized chlorine to the system to obtain 1 to 10 ppm total available chlorine. The recommended stabilized chlorine is typically achieved by mixing 1.5 gallons of Nalco 60620 with 1.0 gallon of sodium hypochlorite (12.5%) Badly fouled systems must be cleaned before treatment is begun

Subsequent Dose: When microbial control is evident, add the appropriate amount of stabilized chlorine to the system to obtain a 1 - 10 ppm total chlorine residual.

C. CONTINUOUS FEED METHOD

Initial Dose: When the system is noticeably fouled, add the appropriate amount of stabilized chlorine to the system to obtain 1 to 10 ppm total available chlorine. The recommended stabilized chlorine is typically achieved by mixing 1.5 gallons of Nalco 60620 with 1.0 gallon of sodium hypochlorite (12.5%). Badly fouled systems must be cleaned before treatment is begun.

Subsequent Dose: Maintain this treatment level by starting a continuous feed of stabilized chlorine to maintain a 1 to 10 ppm total chlorine residual.

NET CONTENTS SHOWN ELSEWHERE ON CONTAINER

RE: Response to questions for 1706-EUN, -EGO, and -EUR
Mann, Juliana
to:
Tracy Lantz
02/11/2011 12:11 PM
Hide Details
From: "Mann, Juliana" <JMann@steptoe.com>

To: Tracy Lantz/DC/USEPA/US@EPA

History: This message has been replied to and forwarded.

The information you requested is identified below in blue. I want to emphasize that the pulp and paper mill systems in which the Nalco products will be used are identical to the systems in which every other registration for pulp and paper mill is used. Only Nalco trained personnel operate the dosing and feed equipment. The dosing and feed equipment are a closed system and there is no worker exposure.

I am getting the final approvals for the labels and data matrix forms and will have those to you shortly.

Thank you,

Juli

Juli Mann | Paralegal Specialist | Steptoe & Johnson LLP |1330 Connecticut Avenue, NW | Washington, DC 20036-1795 | Phone: 202-429-3095 | Fax: 202-429-3902 | jmann@steptoe.com

-----Original Message-----
From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov]
Sent: Thursday, February 10, 2011 3:13 PM
To: Mann, Juliana
Subject: Fw: Response to questions for 1706-EUN, -EGO, and -EUR

A couple of additional questions: We need to know the pH of both of the following:

1) stock chest container that contains virgin materials (pulp)usually used to make better grades of paper. pH

4.5 - 8.5 (most fine paper is manufactured at 7 - 8.5).
2) the broke chest container (pulp) that contains recycled stock. pH 4.5 - 8.5 (in alkaline systems, pH can be lower as a result of microbial spoilage).
Most OxiPro applications are applied to systems running under 'alkaline' conditions (pH 7 - 8.5).

Are we correct that pulp in the stock chest stays for 2-6 hours), and the pulp in the broke chest is present up to 24 hours? I have updated information for the residence time for the pulp in the various chests. Residence time for the stock chest is typically 30 minutes but it may be anywhere from 20 minutes to 6 hours. Residence time for the broke chest is typically 2 hours but it may be anywhere from 1 hour to 24 hours.

Thanks
(Embedded image moved to file: pic31982.jpg)

----- Forwarded by Tracy Lantz/DC/USEPA/US on 02/10/2011 03:09 PM -----

From: Tracy Lantz/DC/USEPA/US
To: "Mann, Juliana" <JMann@steptoe.com>
Date: 02/10/2011 01:00 PM
Subject: Re: FW: Response to questions for 1706-EUN, -EGO, and -EUR

We will also need some additional information on the label. We would like each label to include a chart which indicates how much of your product (in gallons) is added to an amount of EPA registered sodium hypochlorite treated water. The chart should indicate various amounts of your product added to water containing a specified percentage of sodium hypochlorite treated water.

Please reply via email with a pdf of each revised label.

Thanks
(Embedded image moved to file: pic07328.jpg)

Fw: [redacted]
Dennis Edwards to: Melba Morrow, Velma Noble, Tracy Lantz 02/11/2011 09:06 AM

Dennis Edwards, Chief
Regulatory Management Branch 1
Antimicrobials Division
703-308-8087
----- Forwarded by Dennis Edwards/DC/USEPA/US on 02/11/2011 09:05 AM -----

From: Joan Harrigan-Farrelly/DC/USEPA/US
To: Dennis Edwards/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA
Date: 02/10/2011 04:40 PM
Subject: Fw: [redacted]

[redacted]

Internal deliberative

Joan

----- Forwarded by Joan Harrigan-Farrelly/DC/USEPA/US on 02/10/2011 04:38 PM -----

From: Don Lott/DC/USEPA/US
To: Joan Harrigan-Farrelly/DC/USEPA/US@EPA
Cc: Rosemarie Kelley/DC/USEPA/US@EPA, Kim Wilson/DC/USEPA/US@EPA, Brenda Mosley/DC/USEPA/US@EPA, Phil Rosol/RTP/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA
Date: 02/10/2011 02:27 PM
Subject: Fw: [redacted]

Joan-

[redacted]

****
Donald J. Lott, Associate Director
Waste & Chemicals Enforcement Division
(202) 564-2652 ~ lott.don@epa.gov
****

----- Forwarded by Don Lott/DC/USEPA/US on 02/10/2011 02:23 PM -----

From: Kim Wilson/DC/USEPA/US
To: Philip Ross/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA
Cc: Don Lott/DC/USEPA/US@EPA, John Ruggero/R3/USEPA/US@EPA, Brenda Mosley/DC/USEPA/US@EPA

Date: 02/10/2011 02:04 PM
Subject: [redacted]

[redacted]

Thank you,

Kimberly Wilson, Attorney-Advisor
U.S. Environmental Protection Agency, Office of Civil Enforcement
Waste and Chemical Enforcement Division, Pesticides and Tanks Enforcement Branch
phone: 202-564-5607, fax: 202-564-0022

Fw: Response to questions for 1706-EUN, -EGO, and -EUR
Tracy Lantz to: Mann, Juliana 02/10/2011 04:10 PM
Cc: Dennis Edwards
Bcc: Najm Shamim

As per our conversation today, you will revise these labels to include more complete information in the directions for use as per the label for 1448-433 of 3/6/07.
Please be aware that at a later time you may be asked to include that only an EPA registered source for sodium hypochlorite is used.

Regarding the data matrix for Urea, it was discussed that you would revise the matrix to reflect the generic data requirements by listing the guideline #, the study name, "cite-all" and the status as either referring to the RED of the TRED.

Nice to talk to you and Elizabeth.

Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

----- Forwarded by Tracy Lantz/DC/USEPA/US on 02/10/2011 03:28 PM -----

From: Tracy Lantz/DC/USEPA/US
To: "Mann, Juliana" <JMann@steptoe.com>
Date: 02/10/2011 01:00 PM
Subject: Re: FW: Response to questions for 1706-EUN, -EGO, and -EUR

We will also need some additional information on the label. We would like each label to include a chart which indicates how much of your product (in gallons) is added to an amount of EPA registered sodium hypochlorite treated water. The chart should indicate various amounts of your product added to water containing a specified percentage of sodium hypochlorite treated water.

Please reply via email with a pdf of each revised label.

Thanks

Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

Fw: Response to questions for 1706-EUN, -EGO, and -EUR
Tracy Lantz to: Mann, Juliana 02/10/2011 03:12 PM

A couple of additional questions: We need to know the pH of both of the following:

1) stock chest container that contains virgin materials (pulp)usually used to make better grades of paper
2) the broke chest container (pulp) that contains recycled stock.

Are we correct that pulp in the stock chest stays for 2-6 hours), and the pulp in the broke chest is present up to 24 hours?
Thanks

Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

----- Forwarded by Tracy Lantz/DC/USEPA/US on 02/10/2011 03:09 PM -----

From: Tracy Lantz/DC/USEPA/US
To: "Mann, Juliana" <JMann@sleploe.com>
Date: 02/10/2011 01:00 PM
Subject: Re: FW: Response to questions for 1706-EUN, -EGO, and -EUR

We will also need some additional information on the label. We would like each label to include a chart which indicates how much of your product (in gallons) is added to an amount of EPA registered sodium hypochlorite treated water. The chart should indicate various amounts of your product added to water containing a specified percentage of sodium hypochlorite treated water.

Please reply via email with a pdf of each revised label.

Thanks

Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

Re: FW: Response to questions for 1706-EUN, -EGO, and -EUR

Tracy Lantz to: Mann, Juliana 02/10/2011 01:00 PM

Bcc: Najm Shamim

We will also need some additional information on the label. We would like each label to include a chart which indicates how much of your product (in gallons) is added to an amount of EPA registered sodium hypochlorite treated water. The chart should indicate various amounts of your product added to water containing a specified percentage of sodium hypochlorite treated water.

Please reply via email with a pdf of each revised label.

Thanks

Tracy Lantz

Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

FW: Response to questions for 1706-EUN, -EGO, and -EUR
Mann, Juliana
to:
Tracy Lantz
02/10/2011 11:01 AM
Hide Details
From: "Mann, Juliana" <JMann@steptoe.com>

To: Tracy Lantz/DC/USEPA/US@EPA

History: This message has been replied to and forwarded.

From: Mann, Juliana
Sent: Wednesday, February 09, 2011 6:11 PM
To: 'lantz.tracy@epa.gov'
Subject: Response to questions for 1706-EUN, -EGO, and -EUR

Tracy:

I spoke with Linda Fane at Nalco about your questions and have the following information for you:

1. How long does the pulp sit in the slurry from entry point until it is removed for sheet making?

The time can vary based on the grade of paper being made (i.e., cardboard, tissue, printing paper, etc.), the mill size, and the chest size. The chest is the container for the slurry and pulp. There are two types of chests: a stock chest that contains virgin materials usually used to make better grades of paper and a broke chest that contains recycled stock. Pulp in a stock chest may be there for 2 - 6 hours before entering the sheet making process. The pulp in the broke chest may be there for up to 24 hours. It is fed into the system as needed. This is all variable depending on the chest size and type of paper being produced. The turnover in both chests may also be much faster.

2. Is the system open or closed?

There are three different of types of chests used in paper making: open, closed with a removable lid, and closed with a sealed lid that is only opened when the system is down. 1706-EUN, 1706-EGO, and 1706-EUR are used in all three types of chests.

The systems used in the pulp and paper mills into which these products will be used are identical to those using Busan 1215 (EPA Reg. No. 1448-433). Buckman incorrectly identified the active ingredient in Busan 1215 as ammonia. As we pointed out in documents submitted to the Agency, Buckman admits that the active is ammonium sulfate. The risk assessment for Busan 1215 should be identical to the risk assessment for 1706-EUN (Nalco 60620).

I hope this is helpful. Please let me know if you have any additional questions. I'll give you a call Thursday morning to discuss the data matrix forms.

Thank you,

Juli

Juli Mann | Paralegal Specialist | Steptoe & Johnson LLP |1330 Connecticut Avenue, NW | Washington, DC 20036-1795 | Phone: 202-429-3095 | Fax: 202-429-3902 | jmann@steptoe.com

Fw: Letter from Senator Carper to Administrator Jackson Requesting Phone Call

Dennis Edwards to: Velma Noble, Tracy Lantz 02/10/2011 08:39 AM

[redacted]. See correspondence and letter below.

Dennis Edwards, Chief
Regulatory Management Branch 1
Antimicrobials Division
703-308-8087
----- Forwarded by Dennis Edwards/DC/USEPA/US on 02/10/2011 08:38 AM -----

From: Joan Harrigan-Farrelly/DC/USEPA/US
To: Dennis Edwards/DC/USEPA/US@EPA
Date: 02/09/2011 06:45 PM
Subject: Fw: Letter from Senator Carper to Administrator Jackson Requesting Phone Call

[redacted]

Joan

----- Forwarded by Joan Harrigan-Farrelly/DC/USEPA/US on 02/09/2011 06:45 PM -----

From: Rosemarie Kelley/DC/USEPA/US
To: Joan Harrigan-Farrelly/DC/USEPA/US@EPA, chris kaczmarek
Date: 02/09/2011 05:52 PM
Subject: Fw: Letter from Senator Carper to Administrator Jackson Requesting Phone Call

Attorney-Client Privilege

[redacted]

Sent by EPA Wireless E-Mail Services
Cynthia Giles-AA

----- Original Message -----
From: Cynthia Giles-AA
Sent: 02/08/2011 10:23 AM EST
To: Adam Kushner; Rosemarie Kelley
Cc: Matt Bogoshian
Subject: Fw: Letter from Senator Carper to Administrator Jackson Requesting Phone Call

[redacted]

C

Internal deliberative, *Privileged attorney-client communication*

Cynthia Giles
Assistant Administrator
U.S. EPA, Office of Enforcement and Compliance Assurance
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
202-564-2440

----- Forwarded by Cynthia Giles-AA/DC/USEPA/US on 02/08/2011 10:21 AM -----

From:	Arvin Ganesan/DC/USEPA/US
To:	"Cynthia Giles" <Giles-AA.Cynthia@epa.gov>
Cc:	"Carolyn Levine" <Levine.Carolyn@epamail.epa.gov>, "Mr. Sven-Erik Kaiser" <Kaiser.Sven-Erik@epamail.epa.gov>
Date:	02/08/2011 09:38 AM
Subject:	Fw: Letter from Senator Carper to Administrator Jackson Requesting Phone Call

Cynthia,

[redacted]

Thanks.

Sent from my Blackberry Wireless Device

----- Original Message -----
From: "Kotin, Stephanie (Carper)" [Stephanie_Kotin@carper.senate.gov]
Sent: 02/08/2011 09:32 AM EST
To: Arvin Ganesan
Cc: "Reilly, Jim (Carper)" <Jim_Reilly@carper.senate.gov>
Subject: Letter from Senator Carper to Administrator Jackson Requesting Phone Call

Hi Arvin,

I hope you are well. I have attached a letter that Senator Carper would like to get to Administrator Jackson today. In the letter, Senator Carper requests to speak by phone with Administrator Jackson. Please let me know if there is anyone else within your office that we should send the letter to via email today. I have also sent the letter by mail.

Many thanks,
Stephanie Kotin

EPA Biocide Issue_Letter to Administrator Jackson_Feb 8 2011.docx.pdf

Internal deliberative

THOMAS R. CARPER
DELAWARE

United States Senate

WASHINGTON, DC 20510-0803

February 7, 2011

Administrator Lisa Jackson
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC

Dear Administrator Jackson, Lisa

I am writing with regard to an important matter that you and I discussed on October 20th of last year concerning the sale of products in apparent violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). You issued a decision on December 16th, 2010 that made clear that FIFRA does apply to the products we discussed in that call, and that these products must be registered before being sold. I have recently learned that this matter remains unresolved and the products remain available in the marketplace. This raises a question about the EPA's system for appropriate regulation of chemical products such as pesticides and other substances. Continued attention to this matter is necessary to protect the EPA's ability to safeguard the public and to provide the necessary certainty to customers and producers of regulated products.

On December 16th, 2010, the EPA Office of Chemical Safety and Pollution Prevention issued a letter outlining the actions that were needed for Nalco, Inc. to bring two biocidal pesticides, Nalcon 60615 and 60620, into compliance with the requirements of FIFRA. In that letter, the EPA concluded that these ammonia and urea products sold by Nalco, Inc. to the pulp and paperboard industry for use in controlling microbial pests in water systems are indeed pesticides and must be registered under FIFRA. The EPA also stated in that letter that the continued distribution or sale of Nalcon 60615 and 60620 constitutes a violation of FIFRA.

On December 29th, 2010, the EPA's Office of Enforcement and Compliance issued an administrative order to Nalco, Inc. regarding Nalcon 60615 and 60620. In that order, the EPA's Office of Enforcement and Compliance did not require that Nalco, Inc. stop selling the two unregistered pesticides, which the EPA had determined in its December 16th, 2010 letter to be illegal if sold without proper FIFRA registration. By contrast, the December 29th, 2010 Office of Enforcement and Compliance order allowed Nalco, Inc. to continue selling the two unregistered products indefinitely to existing customers, which seems to undermine both EPA's December 16th, 2010 letter regarding Nalcon 60615 and 60620 as well as the basic principles of FIFRA.

Based upon the information available to me, there appears to be an inconsistency between the EPA's December 16th, 2010 decision, and the administrative order issued 13 days later. It appears that allowing a product that has been determined by the EPA to be unregistered to continue to be sold on the market without undergoing proper FIFRA registration and without penalty for having been sold without FIRFA registration is a violation of FIFRA, and thus a cause for serious concern. If FIFRA registration is designed, in part, to protect public health and worker safety, then allowing the sale of a product before registration is complete raises additional questions. I would appreciate the opportunity to discuss this matter again with you so that I may better understand the EPA's actions to date, and what future steps you may take. I understand that you have an extremely busy schedule, but I would be most grateful if we were able to schedule the call for this week.

In the meantime, if you or your staff have any questions, please contact Stephanie Kotin in my office at 202-224-3260. Thank you very much. I look forward to speaking with you about this important issue.

With best personal regards, I am

Sincerely yours,

Tom

Thomas R. Carper
United States Senator

P.S. With all that you have on your plate, I won't talk more than 5-10 minutes of your time; however, I do believe that this is an issue that needs to be addressed. Many thanks.

Response to questions for 1706-EUN, -EGO, and -EUR
Mann, Juliana
to:
Tracy Lantz
02/09/2011 06:10 PM
Hide Details
From: "Mann, Juliana" <JMann@steptoe.com>

To: Tracy Lantz/DC/USEPA/US@EPA

History: This message has been forwarded.

Tracy:

I spoke with Linda Fane at Nalco about your questions and have the following information for you:

1. How long does the pulp sit in the slurry from entry point until it is removed for sheet making?

The time can vary based on the grade of paper being made (i.e., cardboard, tissue, printing paper, etc.), the mill size, and the chest size. The chest is the container for the slurry and pulp. There are two types of chests: a stock chest that contains virgin materials usually used to make better grades of paper and a broke chest that contains recycled stock. Pulp in a stock chest may be there for 2 - 6 hours before entering the sheet making process. The pulp in the broke chest may be there for up to 24 hours. It is fed into the system as needed. This is all variable depending on the chest size and type of paper being produced. The turnover in both chests may also be much faster.

2. Is the system open or closed?

There are three different of types of chests used in paper making: open, closed with a removable lid, and closed with a sealed lid that is only opened when the system is down.

The systems used in the pulp and paper mills into which these products will be used are identical to those using Busan 1215 (EPA Reg. No. 1448-433).

I hope this is helpful. Please let me know if you have any additional questions. I'll give you a call Thursday morning to discuss the data matrix forms.

Thank you,

Juli

Juti Mann | Paralegal Specialist | Steptoe & Johnson LLP |1330 Connecticut Avenue, NW | Washington, DC 20036-1795 | Phone: 202-429-3095 | Fax: 202-429-3902 | jmann@steptoe.com

Fw: Nalco Ashland Buckman - [redacted]

Dennis Edwards to: Velma Noble, Tracy Lantz 02/08/2011 09:54 PM

----- Forwarded by Dennis Edwards/DC/USEPA/US on 02/08/2011 09:54 PM -----

From: Joan Harrigan-Farrelly/DC/USEPA/US
To: Dennis Edwards/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA
Date: 02/08/2011 01:54 PM
Subject: Fw: Nalco Ashland Buckman - [redacted]

----- Forwarded by Joan Harrigan-Farrelly/DC/USEPA/US on 02/08/2011 01:52 PM -----

From: Steven Bradbury/DC/USEPA/US
To: Joan Harrigan-Farrelly/DC/USEPA/US@EPA
Date: 02/08/2011 01:38 PM
Subject: Re: Nalco Ashland Buckman

[redacted]

Sent by EPA Wireless E-Mail Services.
Joan Harrigan-Farrelly

----- Original Message -----
From: Joan Harrigan-Farrelly
Sent: 02/08/2011 12:55 PM EST
To: Steven Bradbury
Subject: Nalco Ashland Buckman

Hi Steve,

[redacted]

Joan

Joan Harrigan Farrelly
US Environmental Protection Agency
Director, Antimicrobials Division
Office of Pesticide Programs
1200 Pennsylvania Ave. N.W. Mailcode 7510P
Washington, DC 20460

Internal deliberative

Physical Address
One Potomac Yard
2777 Crystal Dr.
Arlington, VA 22202
Phone: 703-603-8914

can't print requested attachments via courier for file

RE: 1706-EUN (Nalco 60620)
Mann, Juliana to: Ian Blackwell
Cc: Tracy Lantz

02/04/2011 06:35 PM

2 attachments

EPA-HQ-OPP-2009-1005-0003.pdf EPA-HQ-OPP-2002-0162-0170.pdf

Hi Ian,

Copies of the documents are attached. Please let me know if you need anything else.

Thank you,

Juli

Juli Mann | Paralegal Specialist | Steptoe & Johnson LLP |1330 Connecticut Avenue, NW | Washington, DC 20036-1795 | Phone: 202-429-3095 | Fax: 202-429-3902 | jmann@steptoe.com

-----Original Message-----
From: blackwell.ian@epamail.epa.gov [mailto:blackwell.ian@epamail.epa.gov]
Sent: Friday, February 04, 2011 3:53 PM
To: Mann, Juliana
Cc: Lantz.Tracy@epamail.epa.gov
Subject: 1706-EUN

To: Juli Mann
Steptoe & Johnson

From: Ian Blackwell
US EPA/AD

Dear Juli,

I have begun work on your acute toxicity submission for 1706-EUN (D385696). You cite two documents that I cannot locate. Can you forward copies or internet links of these to me please?

EPA-HQ-OPP-2009-1005-0003
EPA-HQ-OPP-2002-0162-170

Thank You,
Ian Blackwell
Chemistry and Toxicology Team
Product Science Branch

Antimicrobials Division (7510P)
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention (OCSPP)
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

BUCKMAN LABORATORIES, INC.'S REPLY TO NALCO COMPANY'S DEC. 4, 2007 REQUEST THAT EPA RECONSIDER ITS REGISTRATION FOR AMMONIA PRODUCTS AS PRECURSORS TO CHLORAMINE USED IN WATER TREATMENT

AND

BUCKMAN LABORATORIES, INC.'S REQUEST THAT EPA IMMEDIATELY PROHIBIT FURTHER DISTRIBUTION AND SALE OF UNREGISTERED AMMONIA FOR WATER TREATMENT

Michael Boucher

McKenna Long & Aldridge LLP
1900 K Street, NW
Washington, D.C. 20006
(202) 496-7729

Counsel to

Buckman Laboratories, Inc.

September 2, 2008

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

I. Overview

Nalco Company's (hereinafter, "Nalco's") December 4, 2007 "Request That EPA Reconsider Its Registration for Ammonia Products as Precursors to Chloramine Used in Water Treatment and Provide Assurance That There Is No Risk of Enforcement during the Reconsideration and Any Necessary Transition Period" (hereinafter, "Nalco's Petition") is a tirade against EPA's registrations of BCMW (EPA Reg. No. 1448-432) and Busan 1215 (EPA Reg. No. 1448-433), Buckman Laboratories, Inc.'s (hereinafter, "Buckman's") manufacturing-use and end-use ammonia products, respectively. The violence of Nalco's protest tacitly acknowledges Nalco's need to register its own current end-use ammonia product, Nalcon 60620, because Nalcon 60620 and Busan 1215 essentially have the same composition, are used by the same industrial users in the same manner for water disinfection, and are considered interchangeable products in the marketplace. Nalco's Petition ignores the unknown and potentially unreasonable risks presented by the ongoing use of unregistered ammonia to produce monochloramine (hereinafter, "MCA"), including human health risks from unapproved residues of MCA in paper used for food packaging and toxicity to aquatic organisms from MCA residues in industrial waste water.[1] Not surprisingly, Nalco also ignores the significant and ongoing damage being done unfairly to the commercial value of Buckman's ammonia registrations – and to Buckman's ability to recoup its investment in such registrations – by Nalco's ongoing sale of unregistered ammonia with EPA's "temporary" permission, which has lengthened to seven months with no end in sight.

[1] Coincidentally, we have obtained a pre-publication *Federal Register* notice, attached hereto as Exhibit "A," which reports that Zentox Corporation has petitioned the Food and Drug Administration to use MCA as a food additive, specifically, "as an antimicrobial agent in poultry process chiller water" (emphasis added), even though EPA has not registered MCA or ammonia for any such use. This food additive petition underscores the urgent need for EPA to publicly affirm its jurisdiction over MCA – specifically, to prohibit the further distribution and sale of unregistered ammonia for *any* water treatment use, including poultry processing.

To justify the status quo, Nalco offers a series of increasingly erratic and unfocused arguments. Initially, Nalco alleges that ammonia cannot be registered, because it is not an active ingredient (Nalco's Petition at 6-7), but later flip-flops and acknowledges that, in fact, EPA can register a precursor of an active ingredient, where registration of the active ingredient itself is not practical (Nalco's Petition at 9) – exactly as EPA has done with BCMW and Busan 1215, because the registration of MCA itself for water treatment is impractical. Then, Nalco agrees that combining ammonia and sodium hypochlorite produces MCA (Nalco's Petition at 4), in a chemical reaction known since the early 1900s, but alleges that MCA is not an active ingredient that is separate from "chlorine" (hypochlorous acid) (Nalco's Petition at 8-9, 11), even though the production of MCA is a reaction that is not considered reversible (*i.e.*, once formed, MCA does not readily break down into, or otherwise produce, ammonia and hypochlorous acid/hypochlorite ions), and despite that EPA and industry recognize MCA as a distinct active ingredient with valuable properties that are different from those of hypochlorous acid. Nalco also plays variations on the foregoing theme, specifically, that ammonia "sequesters" and releases "chlorine" by a novel chemical process that Nalco never explains (Nalco's Petition at 4, 6-7, 11-12), and that ammonia is only an adjuvant used with "chlorine" and, thus, requires no registration (Nalco's Petition at 15), even though ammonia reacts completely with sodium hypochlorite to form a new active ingredient, MCA, and, thus, does not hold or release hypochlorous acid and does not resemble any adjuvant.

For the foregoing reasons, as articulated and explained in this petition, we respectfully request pursuant to section 553(e) of the Administrative Procedures Act (5 U.S.C. § 553(e)) that EPA deny Nalco's Petition and immediately prohibit further distribution and sale of unregistered ammonia for water treatment. Nalco has asked for time to register ammonia but neither needs

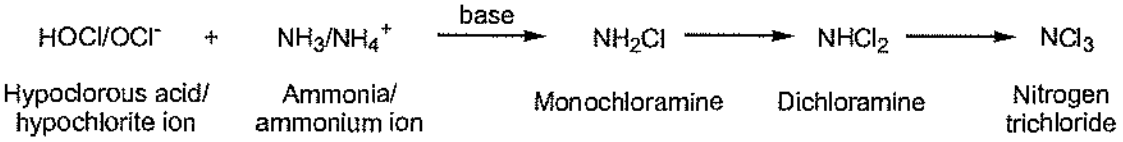
nor deserves any additional time. Nalco has had notice of EPA's policy on the registration of ammonia for water treatment since the Agency's registration of Buckman's ammonia products on March 6, 2007. Since then – a period of 18 months – Nalco has found ample time to make two lengthy and duplicative submissions and one responsive submission to EPA in order to subvert the Agency's registration of Buckman's ammonia products. Neither of Nalco's original filings ever had a likelihood, much less a *certainty*, of persuading EPA to revoke its considered registrations of ammonia, which Nalco knew at the time of its filings. Indeed, as recently as July 15, 2008, the Agency amended Buckman's registration of Busan 1215 to add a new use (industrial water systems), which suggests no intent by EPA to grant either of Nalco's original requests to revoke Buckman's ammonia registrations. Accordingly, in addition to filing petitions with EPA, Nalco also should have filed or, at a minimum, prepared itself fully to file an application to register ammonia sometime during the past 18 months. If, as it appears, Nalco has chosen instead to focus wholly on a speculative petition effort intended to manipulate EPA into allowing Nalco to remain on the market without an ammonia registration and, thereby, to continue to compete with Buckman unfairly and, specifically, to erode its customer base, the Agency should not now reward Nalco for its gamesmanship with any additional time to register ammonia.

In preparing this petition on behalf of Buckman, we consulted with scientists and regulatory consultants at Technology Sciences Group Inc., namely, Dr. Robert Stewart, Vice President and Managing Director, and Dr. David Brookman, Director of Environmental Chemistry. Drs. Stewart and Brookman have reviewed and concur in our technical representations in this petition.

II. **Both Nalco and Buckman sell ammonia for use in proprietary systems in which ammonia and sodium hypochlorite react to form MCA, which is the active ingredient supplied by each system for water treatment.**

Use of either Nalco's or Buckman's end-use ammonia product, as labeled, generates the same main active ingredient, MCA (monochloramine), which is formed by a chemical reaction that occurs at the time of use. The general reaction is as follows:

Figure 1



The reaction is normally terminated at the stage where MCA is formed, but dichloramine and nitrogen trichloride also may occur.

The nominal active ingredient in Nalco's end-use ammonia product (Nalcon 60620) is "ammonium sulfate" and in Buckman's end-use ammonia product (Busan 1215) is "ammonia (total)," which derives from an aqueous mixture of ammonia and ammonium sulfate. Therefore, both products provide ammonia or ammonium ions in the reaction shown in Figure 1 above, and both lead to the in-situ generation of one or more chloramines.

According to its label, attached hereto as Exhibit "B," Nalcon 60620 is an unregistered formulation consisting of 20% ammonium sulfate and 80% "constituents ineffective as spray adjuvants," presumably water. Nalco sells Nalcon 60620 as part of its "OxiPRO™ Deposit Control Technology" and, specifically, for use in Nalco's "OxiPRO Feed System," which is illustrated and described in a Nalco proposal and a Nalco slide presentation attached hereto as Exhibits "C" and "D," respectively. Nalco's label for Nalcon 60620 and Nalco's materials on the OxiPRO Feed System describe a process in which a Nalco technician adds Nalcon 60620 to

sodium hypochlorite in a molar ratio between 1:1 and 2:1, at a controlled temperature, under alkaline conditions to produce a "stabilized oxidant," which Nalco does not identify but which is MCA, upon examination.

Based upon the available information, use of Nalco's OxiPRO Feed System involves the following preparative steps:

(1) Aqueous sodium hypochlorite (12.5%) is added to aqueous sodium hydroxide (50%) to produce an initial mixture of sodium hypochlorite, sodium hydroxide, and water (pH ≥ 7).

(2) To this initial mixture, aqueous ammonium sulfate (20%) is added in a molar ratio between 1:1 and 2:1 to produce a second mixture containing chloramines, sodium sulfate, sodium chloride, and water.[2]

(3) The second mixture is diluted with additional water to produce a lower concentration of MCA, presumably 10-12 parts per million (hereinafter, "ppm") measured as total chlorine, which is the target stated in Nalco's June 23, 2008 slide presentation (Ex. D at 9). The diluted mixture is promptly added to the customer's process water at the desired point(s).

According to its label, attached hereto as Exhibit "E," Busan 1215 is an EPA-registered formulation (EPA Reg. No. 1448-433) consisting of 7.59% ammonia and 92.41% "inert ingredients." Buckman sells Busan 1215 as part of a proprietary water disinfection system for pulp and paper mills and industrial cooling systems mill, specifically, Buckman's "Busan 1215 Feed System." The Busan 1215 Feed System is illustrated in a photograph, a line drawing, and a process diagram attached hereto as Exhibits "F," "G," and "H," respectively.

[2] Nalco's process description does not permit estimation of the exact composition of the second mixture, which may contain dichloramine and possibly even nitrogen trichloride in addition to MCA.

In the Busan 1215 Feed System, a Buckman technician adds 0.5 oz. of Busan 1215 to 1 oz. of sodium hypochlorite (≤ 15% wt/wt) to produce MCA under conditions of controlled temperature and pH. Specifically, use of the Busan 1215 Feed System involves the following preparative steps:

(1) Aqueous ammonia (pH > 9) is diluted with water. Unlike the OxiPRO Feed System, the Busan 1215 Feed System does not require the addition of a base, such as sodium hydroxide, because basic conditions are maintained by the ammonia.

(2) The initial mixture is added to aqueous sodium hypochlorite (12.5%) at a minimum 3:2 molar ratio of sodium hypochlorite to ammonia to produce a second mixture of MCA, sodium chloride, and water.

(3) The second mixture is diluted with additional water to achieve a concentration of 0.5 to 1 ppm of MCA in excess of the system oxidant demand (maximum of 5 ppm measured as total chlorine), and the diluted mixture is promptly added to the customer's process or cooling water at the desired point(s).

When Busan 1215 is used as directed in the Busan 1215 Feed Process, the sodium hypochlorite/hypochlorous acid is completely consumed, and chloramines other than MCA do not form readily. For this reason, MCA is the sole oxidant (*i.e.*, active ingredient) in solutions prepared from Busan 1215.

In sum, a careful examination of Nalco's OxiPRO Feed System and Buckman's Busan 1215 Feed System shows that in both systems, ammonia and sodium hypochlorite react to produce chloramines. The Buckman system generates MCA, and the Nalco system generates MCA and possibly also other chloramines. The basic chemistry underlying both processes is familiar and has been known since the early 1900s (U.S. Envtl. Protection Agency, Office of

Water, "Alternative Disinfectants and Oxidants Guidance Manual" (April 1999) at 6-1, *available at* http://www.epa.gov/OGWDW/mdbp/alternative_disinfectants_guidance.pdf; hereinafter, "Oxidants Manual"). In its December 4, 2007 petition, Nalco does everything but explain in accurate chemical terms how ammonia is used in Nalco's and Buckman's water treatment systems. Accordingly, Nalco's avoidance of chemistry obscures the fact that MCA is the pesticidal active ingredient that results from both Nalco's and Buckman's use of ammonia for water treatment.

III. Registration of ammonia is necessary, because MCA is too unstable to exist as a marketable commodity, no EPA-approved sodium hypochlorite label has instructions for use with ammonia to safely produce MCA, and the continued use of unregistered ammonia to produce MCA presents unnecessary and potentially unreasonable risks to human health and the environment.

Over a period of a day or so, without any modification of pH or Cl_2:N ratio, MCA will degrade slowly to dichloramine, specifically, to a ratio of 43% MCA to 57% dichloramine, which is itself unstable and also has an unpleasant taste and odor to humans (Oxidants Manual at 6-2 to 6-3). For this reason, it is impractical to bottle and sell MCA as a commercial pesticide product, and we have been unable to find any EPA registration of MCA, past or present. Instead, since the 1930s, the universal practice has been to generate MCA in situ (*i.e.*, at the site of use) for use as a water disinfectant (Oxidants Manual at 6-1).

In 1986, EPA's Environmental Appeals Board affirmed the Agency's authority to register a "parent chemical" or "immediate precursor" that "does not itself have pesticidal properties" but "produces pesticidal action at the site of application," when "the actual pesticide required to be regulated under the Federal Insecticide, Fungicide... cannot exist as a marketable commodity," and when the parent chemical/immediate precursor is "the only logical chemical through which the use of the [actual] pesticide can be regulated" (*In the Matter of: South Coast Chemical, Inc.*, 2 E.A.D. 139, 145 (1986); included as Exhibit "I" hereto). Under the foregoing rationale,

ammonia should be registered, despite its lack of pesticidal properties, because ammonia produces pesticidal action at the site of application, *i.e.*, produces MCA at the use site; because MCA cannot exist as a marketable commodity, due to its instability; and because ammonia is the only logical chemical through which the use of MCA can be regulated.

Nalco proposes, in effect, that the registration of sodium hypochlorite alone is sufficient to regulate the use of MCA, but there is no EPA registration of sodium hypochlorite that addresses use with ammonia to produce MCA. Nalco's five sodium hypochlorite registrations (EPA Reg. Nos. 1706-171, -179, -238, -20001, -20002), attached hereto as Exhibit "J," are silent about any use with ammonia, as is the registration of "Sunny Sol® 150" (EPA Reg. No. 1744-20001), attached hereto as Exhibit "K," a registered sodium hypochlorite product that Nalco recommends for use with ammonia in Nalco's OxiPRO Feed System. Thus, maintaining the status quo – Nalco's plan – will not ensure that users of ammonia and sodium hypochlorite to produce MCA will have appropriate labeling, including warnings, precautions, and directions for use, that EPA has reviewed and approved to ensure the safe use of MCA as a pesticide.

A theoretical alternative to the status quo is to amend all existing sodium hypochlorite registrations either to prohibit use with ammonia or to specifically address such use to produce MCA, but this is an impractical solution, because there are 211 registrants with 379 registrations of sodium hypochlorite. On the other hand, ammonia has only one registrant, Buckman, and only one end-use registration, for Busan 1215, which is registered specifically for use with sodium hypochlorite to produce MCA; indeed, ammonia currently has no other "pesticidal" use. Accordingly, to regulate the use of MCA, EPA's best and only practical option is to register ammonia as a precursor of MCA, as the Agency has done in Buckman's case and now needs to do in the case of Nalcon 60620 and all other unregistered ammonia for water treatment.

EPA also needs to register ammonia to ensure that the use of MCA does not present unreasonable adverse effects on the environment. In the case of Busan 1215, for example, EPA required Buckman, as a condition of registration, to obtain a letter from the Food and Drug Administration regarding whether MCA requires a food additive tolerance under section 409 of the Federal Food, Drug, and Cosmetic Act for any residues of MCA in paper used for food packaging. In addition, MCA is toxic to aquatic organisms, and Buckman's label includes directions for use that limit the quantity of MCA added to the customer's process or cooling water to a maximum of 5 ppm measured as total chlorine and that tell users how to neutralize any MCA detected in effluent. In other words, by registering Busan 1215, EPA was able to ensure that the MCA produced with Busan 1215 was used safely, specifically, so as to prevent unapproved residues in food packaging and aquatic toxicity from residues in effluent.

Conversely, EPA has not evaluated the use of any unregistered ammonia product to produce MCA, and has no assurances with respect to any residues of MCA in food packaging or waste water. Thus, unnecessary and potentially adverse risks to human health and the environment remain. For example, Nalco's OxiPRO Feed System releases 10-12 ppm of MCA measured as total chlorine to the customer's process water, which is more than *twice* the concentration of MCA permitted by EPA on Buckman's end-use ammonia label (Ex. D at 9).

IV. Ammonia does not sequester or release "chlorine" and is not an adjuvant; ammonia does react with sodium hypochlorite to produce an entirely new active ingredient, MCA, which has distinct properties from hypochlorous acid.

Nalco identifies chemical substances (cyanuric acid, diethanolamine, disodium zinc ethylene diamine tetracetate dehydrate, ammonium carbamate) and product types (stabilizers, sequestrants, synergists) that allegedly "perform similar functions" as ammonia but are not registered, implying that EPA has acted irrationally in registering Busan 1215 (Nalco's Petition at 12-15). Nalco's reasoning is flawed and misleading, however, because ammonia is a

precursor of MCA – specifically, a reactant in its formation – not an adjuvant. Ammonia reacts with sodium hypochlorite in water to form a different chemical compound, MCA, and both the ammonia and the sodium hypochlorite are consumed in the reaction. Conversely, the chemical substances and products that Nalco identifies do not react to form a different chemical compound or compounds and remain chemically unchanged.

Nalco perpetuates a self-serving fiction that ammonia merely "sequesters" and, later, releases "chlorine" (hypochlorous acid) (Nalco's Petition at 4, 6-7, 11-12; Ex. C at 7; Ex. D at 7). This characterization is false for several reasons. First, the use of Nalco's OxiPRO Feed System unmistakably produces MCA, which EPA recognizes as a separate and distinct active ingredient from chlorine (Oxidants Manual at 2-30, 6-1). Second, a chemical reaction takes place when Nalco's ammonia product is used. The reaction produces MCA and possibly other chloramines. Third, the chemical reaction that produces MCA is not considered reversible. In other words, once the chloramine (or -amines) have formed through chemical reaction, they cannot break down readily into, or otherwise produce, ammonia and hypochlorous acid/hypochlorite ions.[3]

Furthermore, MCA and chlorine have different chemical and antimicrobial properties, and such differences favor MCA over chlorine in certain applications. For example, MCA is increasingly used as a secondary disinfectant in drinking water distribution systems, because it decays more slowly and produces substantially fewer disinfection byproducts than chlorine (Oxidants Manual at 6-10, 6-27 to 6-29).

MCA and chlorine also have different mechanisms by which they inactivate microorganisms. MCA reacts with four amino acids (cysteine, cystine, methionine, and

[3] MCA can hydrolyze very slowly in a process that can form chlorine. Also, making a solution of MCA strongly acidic (pH < 1-2) can cause the MCA to decompose and generate some chlorine. Under the conditions under which MCA is used for water treatment, no such hydrolysis or decomposition should occur.

tryptophan), and the mechanism of inactivation is thought to involve inhibition of proteins or protein mediated processes, such as respiration (Oxidants Manual at 6-12). Also, MCA typically requires "multiple hits" upon bacterial cells before cell death (Oxidants Manual at 6-12). By contrast, chlorine is capable of producing lethal events at or near the cell membrane and of affecting DNA (Oxidants Manual at 2-35). In bacteria, chlorine adversely affects cell respiration, transport, and possibly DNA activity (Oxidants Manual at 2-35). Accordingly, MCA does not kill microorganisms by "releasing" chlorine, or MCA would have the same antimicrobial properties as chlorine, and it does not.

Furthermore, EPA has determined that MCA does not control as many different microorganisms as chlorine and hypochlorous acid (Oxidant Manual at 2-36 to 2-39, 6-13 to 6-15). Accordingly, Nalco's unqualified antimicrobial claims for its OxiPRO Feed System (Ex. C; Ex. D) imply a level of microbial control that is not provided by MCA. The only way to clearly separate appropriate claims for MCA from those for chlorine and hypochlorous acid is to register Nalco's ammonia and all other ammonia for water treatment and to properly attribute the antimicrobial claims for MCA to such ammonia registrations.

V. EPA should promptly deny Nalco's Petition to revoke Buckman's ammonia registrations, because the Agency has properly registered Buckman's ammonia as a precursor of MCA for water treatment.

As explained in section II above, a scientific analysis of how ammonia is used in Nalco's and Buckman's proprietary water treatment systems shows unambiguously that MCA is the active ingredient released by these systems for water treatment. As explained in section III above, MCA is too unstable to be bottled and sold as a marketable commodity and, therefore, is universally produced in situ. Accordingly, there are no active or inactive EPA registrations of MCA by which EPA can control the potential risks from using MCA, which include unapproved residues in food packaging and aquatic toxicity. To address these potential risks, EPA must

register one or both of the immediate precursors of MCA, sodium hypochlorite or ammonia. With one registrant (Buckman), one end-use registration (Busan 1215), and no other pesticidal uses, ammonia is the best and only practical candidate for registration, which EPA has recognized by registering Buckman's ammonia products after careful consideration. Furthermore, as explained in section IV above, ammonia is a precursor of MCA, not an adjuvant: Ammonia reacts with sodium hypochlorite to produce a new active ingredient, MCA, which has distinct properties from hypochlorous acid, this reaction is not reversible, and ammonia does not sequester or release hypochlorous acid. Thus, EPA's decision to register ammonia as a precursor of MCA has no relationship to the Agency's past or present regulatory handling of the adjuvants identified by Nalco. For all of the foregoing reasons, EPA properly granted registrations to Buckman's ammonia products, and Buckman respectfully requests that the Agency deny Nalco's Petition request to revoke Buckman's registrations.

VI. EPA should immediately prohibit further distribution and sale of unregistered ammonia for water treatment, because the continued sale of unregistered ammonia to the same customers for, and for the same uses as, Buckman's registered ammonia presents unnecessary and potentially unreasonable risks to human health and the environment, contradicts and undermines the Agency's proper registration of Buckman's ammonia, and unfairly damages the commercial value of Buckman's registrations.

If EPA has properly registered Buckman's ammonia as a precursor of MCA for water treatment, then Nalco's ammonia also must be registered, which Nalco has acknowledged by its violent reaction to the registration of BCMW and Busan 1215. As demonstrated in section II above, Nalcon 60620 and Busan 1215 are commercially interchangeable: Both products are used by the same people for the same purpose, namely, as a source of ammonia to produce MCA in situ for the disinfection of industrial water. Nalco's label description of Nalcon 60620 as a "stabilizer for active chlorine sources" is dishonest in scientific terms, because it does not match the chemical reactions that actually occur in the OxiPRO Feed System.

By letter dated February 7, 2008, attached hereto as Exhibit "L," however, EPA has "temporarily" accepted Nalco's erroneous description of Nalcon 60620 as a chlorine stabilizer, pending further investigation. Since then – seven months and counting – Nalco has aggressively marketed and sold unregistered ammonia to commercial users, who continue to produce and use MCA without any EPA oversight, specifically, while Nalco has not had to demonstrate, and EPA has not had the opportunity to confirm, that the use of Nalcon 60620 to produce MCA adequately addresses the potential human health and environmental risks from the use of MCA.

Meanwhile, Buckman cannot explain EPA's differential treatment of Nalcon 60620 and Busan 1215 to customers, and because these products are interchangeable in the marketplace, many customers now perceive EPA's registration of Busan 1215 as pointless and unnecessary – an impression that has been reinforced by EPA's failure to date to require the registration of any ammonia products for water treatment other than Buckman's. EPA's inaction not only contradicts Buckman's ammonia registrations, it unfairly damages their commercial value. Accordingly, the longer that EPA discriminates against Buckman by requiring the registration of Buckman's ammonia while allowing all competitive ammonia products for water treatment to be sold without registration, the better it serves Nalco's desire to delay registration, the harder it is for Buckman to salvage its considerable investment to register ammonia, and the longer the public goes without assurance that MCA is being used safely, which is provided only by EPA's registering all ammonia for water treatment. Furthermore, Nalco has had more than enough time to register ammonia and has chosen instead to focus solely on a petition process to delay registration for as long as possible while it continues to compete unfairly against Buckman in the marketplace with unregistered ammonia that reflects no regulatory costs. Thus, EPA should not reward Nalco's delaying tactics and opportunism with any additional time to register. For all of

these reasons, Buckman respectfully requests that EPA immediately prohibit further distribution and sale of unregistered ammonia for use in water treatment.

VII. Conclusion

Buckman has demonstrated that its and Nalco's ammonia products are used in the same way (as precursors to produce MCA) by the same industrial users (primarily, pulp and paper mills, but also facilities with industrial cooling systems), who perceive the two products as interchangeable for water treatment applications (disinfection of mill and industrial cooling water). Buckman has shown that its and Nalco's ammonia products do not "sequester" or release hypochlorous acid and are not adjuvants, and that EPA has the authority to register ammonia products as precursors of MCA, since the registration of MCA itself for water treatment is impractical. Buckman also has shown that only the registration of *all* ammonia products for water treatment will ensure that EPA has evaluated any potential risks from the use of MCA and restore a level playing field in the marketplace for industrial water disinfection. For these reasons, as explained in this petition, we renew our request that EPA deny Nalco's Petition and immediately prohibit further distribution and sale of unregistered ammonia for water treatment. We welcome an opportunity to discuss our petition with EPA.

Respectfully submitted,

Michael Boucher

McKenna Long & Aldridge LLP
1900 K Street, NW
Washington, D.C. 20006
(202) 496-7729

Counsel to

Buckman Laboratories, Inc.

Dated: September 2, 2008

EXHIBIT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2008F0462]

Zentox Corp.; Filing of Food Additive Petition

AGENCY:
Food and Drug Administration, HHS.

ACTION:
Notice.

SUMMARY:
The Food and Drug Administration (FDA) is announcing that Zentox Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of monochloramine as an antimicrobial agent in poultry process chiller water.

DATES:
Submit written or electronic comments on the petitioner's environmental assessment by [insert date 30 days after date of publication in the Federal Register).

ADDRESSES:
Submit written comments to the Division of Dockets Management (HFA305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:
Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 207403835, 3014361071.

SUPPLEMENTARY INFORMATION:
Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8A4775) has been filed by Zentox Corp., c/o Burdock Group, 801 North Orange Ave., suite 710, Orlando, FL 32801. The petition proposes to amend the food additive regulations in part 173Secondary Direct Food Additives Permitted in Food for Human Consumption (21 CFR part 173) to provide for the safe use of monochloramine as an antimicrobial agent in poultry process chiller water.

The potential environmental impact of this petition is being reviewed. To encourage public participation consistent with regulation issued under the

National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see DATES and ADDRESSES) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required, and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.51(b).

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at http://www.regulations.gov.

Dated: August 27, 2008.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 08????? Filed ????08; 8:45 am]BILLING CODE 416001S

(FR Doc. 2008-20293 Filed 08/29/2008 at 8:45 am; Publication Date: 09/03/2008]

EXHIBIT B

NALCO

Nalcon® 60620

Stabilizing solution for use with active chlorine sources.

Nalcon® 60620 is a unique stabilizer for active chlorine sources. Nalcon® 60620 stabilizer minimizes the decomposition of active chlorine caused by the high chlorine demand of papermaking waters. When used as directed, Nalcon® 60620 stabilizer reduces the quantity of active chlorine that reacts with dissolved and suspended organics, thereby maximizing compatibility with sensitive process additives. By reducing interactions with sources of active chlorine demand (including sensitive process additives such as optical brighteners, retention aids, and wet and dry strength aids) Nalcon® 60620 optimizes chlorine stabilization. Nalcon® 60620 is intended for use in process waters used in the manufacture of both food and non-food paperboard.

PRINCIPAL FUNCTIONING AGENTS:

Ammonium sulfate	20.0%
CONSTITUENTS INEFFECTIVE AS SPRAY ADJUVANTS	80.0%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

- IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Get medical attention if irritation occurs and persists.
- IF ON SKIN: Rinse skin immediately with plenty of water for 15-20 minutes. If symptoms develop, seek medical attention.
- IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water. Do not induce vomiting without medical advice. Do not give anything by mouth to an unconscious person.
- IF INHALED: First aid is normally not required. Remove to fresh air, treat symptomatically. If symptoms develop, seek medical advice

NOTE TO PHYSICIAN

Based on the individual reactions of the patient, the physician's judgment should be used to control symptoms and clinical condition. Have the product container or label with you when calling a Poison control Center or doctor or going for treatment.

NET CONTENTS SHOWN ELSEWHERE ON CONTAINER

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Warning: May cause irritation to the eyes, and skin. Do not get in eyes, on skin, or on clothing. Do not take internally. Use with adequate ventilation Rinse thoroughly with water after handling. Remove contaminated clothing and wash clothing before reuse. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves (rubber, chemical resistant) when handling.

STORAGE AND DISPOSAL

Store in suitable, tightly closed, labeled containers. In case of a spill, soak up spill with absorbent material and clean contaminated surfaces with water or aqueous cleaning agents. Wastes resulting from the use of this product are not subjected to federal regulation. Consult state or local regulations for any additional handling, treatment or disposal requirements. For disposal, contact a properly licensed waste treatment, storage, disposal or recycling facility.

DIRECTIONS FOR USE

Nalcon® 60620 stabilizer can be mixed with a source of active chlorine prior to paper machine waters, or added to a system currently treated with active chlorines.

If Nalcon® 60620 stabilizer is pre-blended with the active chlorine source, the mixture should then be added to process water streams at or immediately prior to a point of sufficient mixing, such as the main water inlet, the fan pump, or wire pit. Use a metering pump of sufficient accuracy on each, liquid piped with back-flow prevention, to produce the liquid blend using an in-line-mixing device (such as a static T mixer).

DOSAGE: For optimal stabilization, add Nalcon 60620 stabilizer to active chlorine at a molar ratio between 1:1 and 2:1. For food contact, use no more than needed to achieve the desired effect.

NOT FOR USE IN FISH BEARING WATERS.

Nalco Company
1601 West Diehl Road
Naperville, IL 60563-1198
EMERGENCY PHONE NO. (800) 424-9300

Revised: 07/25/2007

THIS PRODUCT IS NOT REGULATED DURING TRANSPORTATION

NALCO

NALCON(R) 60620

Proprietary Halogen Stabilizer

LOT NO.	DENSITY	NET WEIGHT
	9.1 lb/gal	

FDA: 21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods and 21 CFR 176.180 Components of paper and paperboard in contact with dry foods., 21 CFR 176.210 Defoaming agents used in the manufacture of paper and paperboard. Hazardous ingredients may be listed under State Right-to-Know.

KOSHER: This product has been certified as KOSHER/PAREVE for year-round use INCLUDING THE PASSOVER SEASON by the CHICAGO RABBINICAL COUNCIL

CAUTION! May cause irritation with prolonged contact. Do not get in eyes, on skin, on clothing. Do not take internally. Use with adequate ventilation. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water. Wear suitable protective clothing.

STATE RIGHT-TO-KNOW:
Inorganic salt ... Proprietary

ATTENTION: For more information refer to the material safety data sheet. Empty containers may contain residual product. DO NOT reuse containers unless properly reconditioned.

NFPA	HMIS

Degree of Hazard
4 = Extreme
3 = High
2 = Moderate
1 = Low
0 = Insignificant
* = See MSDS UNLESS OTHERWISE INDICATED

MADE IN U.S.A.

HEALTH	1
FLAMMABILITY	0
PHYSICAL HAZARD	0
PERSONAL PROTECTION	*

EMERGENCY TELEPHONE NUMBER(S): (800) 424-9300 (24 Hours) CHEMTREC

Nalco Company -Plant 140
Ellwood City North Plant 125 Nalco Way, ELLWOOD CITY, PA, USA 16117
724-752-6200

Material: 60620.91 Generated: 10/29/2007

U.S. DOT Shipping Name: PRODUCT IS NOT REGULATED DURING TRANSPORTATION

EXHIBIT C

NALCO

OxiPRO™

OxiPRO™ Deposit Control Technology PROPOSAL

[redacted]

[redacted]

[redacted]

Production Leader

[redacted]

Thank you for the opportunity to review our **OxiPRO™ Deposit Control Technology**.

Please find enclosed our proposal outlining how OxiPRO™, can benefit the[redacted]

[redacted]

Nalco's OxiPRO™ Deposit Control Technology offers improved paper machine efficiency by controlling microbial-based deposits through:

- Innovative chlorine stabilizing chemistries
- A combination of new and unique proactive monitoring tools,
- Application expertise & strategies to maximize performance

Resulting in:

- Improved system stability
- Reduced treatment cost
- Reduce sheet defects
- Increased uptime.

We thank you once again for this opportunity to work with you and look forward to discussing this proposal with you in more detail.

Sincerely,

[redacted]

Nalco Company

CC [redacted]

[redacted]

NALCO

OxiPRO™

OxiPRO™ Deposit Control Technology PROPOSAL

[redacted]

Introduction:
The following is a proposal for OxiPRO™ microbiological control program for [redacted].

Nalco's OxiPRO™ Deposit Control Technology is a stabilized oxidant program. It takes an oxidant that has been blended with caustic on site and stabilizes it with our unique chemistry. A specially designed feed system insures the oxidant is completely stabilized. Nalco's online microbiological monitoring unit provides continuous real time results for proactive control.

Nalco's OxiPRO™ innovative oxidant stabilizer program can provide [redacted] with these benefits:

- The most economical microbiological treatment program for neutral conditions
- Consistently meet or extend boil out target periods.
- Greater system assurance through online monitoring
- Longer equipment life due to a less corrosive chemistry.
- Improved runnability of machine and converting due to less holes/deposits creating sheet defects and breaks

Specific Potential Benefits for the [redacted] Mill Operation:

- **Innovative chlorine stabilizer**
  Nalco has several stabilized oxidants that can be utilized for your system. Testing and Nalco experience has shown that Nalco 60620 is most effective in your system.

- **Improved Silo treatment strategies to minimize biomass**
  Nalco's OxiPRO™ program creates stabilize oxidants that provide extended control even in the most demanding systems. Nalco will employ a slug feed to help improve system cleanliness while minimizing adverse effects of high free chlorine residuals on machine performance and paper quality.

- **Real-time microbial monitoring for greater system assurance and optimization.**
  This program comes with Nalco's new patent pending online continuous microbiological monitoring unit for optimum proactive control. Real time MB monitoring allows for immediate response before a system upset can occur.

OxiPRO™ Deposit Control Technology PROPOSAL

[redacted]

Improved Machine Efficiency.
Eliminating biological upsets will help improve wet end stability. Improved machine and converting runnability due to less microbiological holes/deposits.

Program Objective and Success Criteria:

- Be safe and reliable at all times
- Maintain a clean paper machine system with no microbiological deposits.
- Provide timely monitoring data for proactive control.
- Have no negative impacts on wet end chemistry.
- Provide service needed to maintain the program in peak performance and document the results

Program Cost:
The program would be billed on a price/ton basis. [redacted]

Nalco 60620 and Nalco BL 409	$2.35/swt
Bleach, 12.5%	Supplied by [redacted] in totes or bulk

This pricing also includes:

- One feed systems capable of feeding 4 addition points.
- One OxiPRO™ Monitoring unit.
- Nalco service and support program.
- Nalco maintains ownership of the feed and monitoring equipment.
- A water softener if needed.

[redacted] would provide the following:

- Clean water for final dilution.
- Assistance installing the equipment.
- Electrical and piping connections to the units and feed points.
- Wireless or Ethernet connection for monitor information transfer.
- Bleach in totes or bulk storage on [redacted]

Discussion:
Nalco's OxiPRO™ Deposit Control Technology program for [redacted] includes feed equipment, monitoring equipment, a stabilized oxidant program, and on-site service. This discussion will provide details and supporting information for the proposed program.

Stabilized Oxidant Chemistry:
OxiPRO™ Technology combines a stabilizer (Nalco 60620) blended on site by the feed skid with commercially available 12.5% sodium hypochlorite and NaOH.

[redacted]

[redacted]

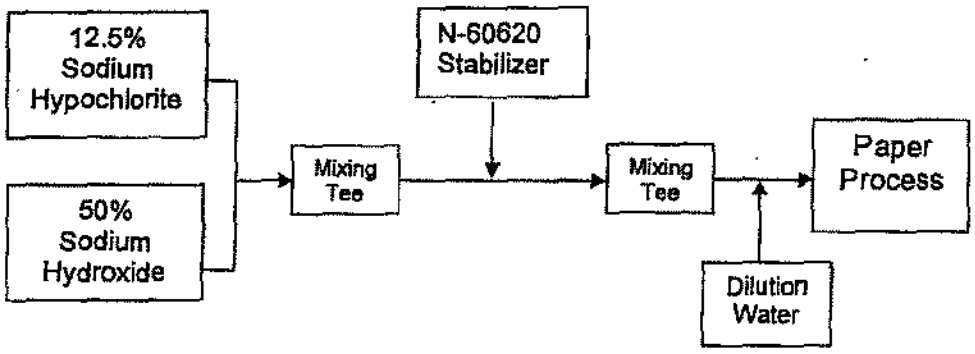
The stabilizer is determined by a screening performed at the Nalco Technical Facility utilizing your furnish.

The stabilizer of choice from the testing is Nalco 60620. It showed to have the best low concentration kill as well as the best high concentration persistence when compared with the other products.

This product has shown to be effective in similar environments both in the lab and in mill experience. This product is currently being utilized in multiple tissues and towel mills with great success.

OxiPRO™ Feed System

The feed skid blends the chemistries in the appropriate ratios and delivers the stabilized oxidant to the paper process. Below is a simple flow sheet of the feed skid operation. The feed skids can be designed to run in a slug configuration or a continuous operation. For the [redacted] system we recommend utilizing a slug feed operation to assure proper coverage and cost effectiveness.



Addition Points

Nalco recommends the following addition points for the [redacted] operation. These points could change or be reduced pending system requirements as the program is optimized.

1. TM Silo
2. TM Shower Water Tank

[redacted]

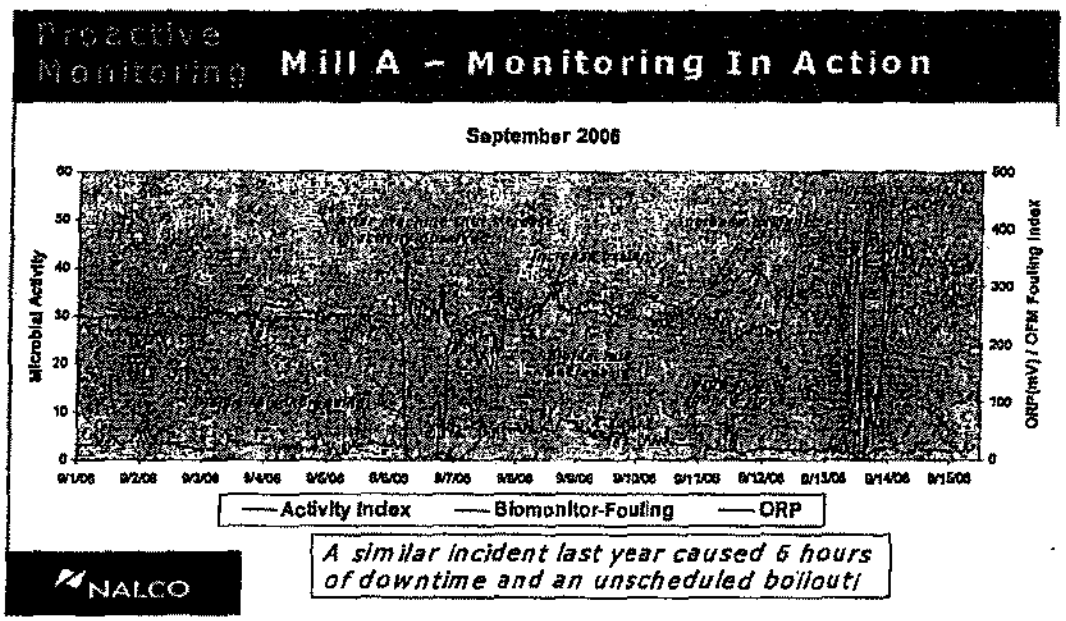
OxiPRO™ On-Line Monitoring

Nalco's on line monitor is an important part of this system. This unit was developed by Nalco to provide real time information and true proactive control. The unit continuously monitors four system conditions:

1. Microbiological activity level
2. Overall fouling rate
3. ORP
4. pH

The unit monitors a head box or white water system side stream and the sample can be returned back to the process. An internet connected computer or cell phone can access the data immediately either on-site or remotely. Target control ranges can be set for each parameter and the unit will send alarms to a computer or by cell phone text message alerting the local team to take action as required.

The following is actual data from the monitor that a Nalco representative used to prevent a lost time upset. Similar incidents at this mill before the monitor was installed caused six hours of lost time.



Traditional Microbiological Monitoring
In addition to the online monitoring, Nalco performs standard microbial surveys using plate counts and chlorine residuals as required. ATP monitoring is also used to help calibrate the monitor target control ranges and troubleshooting variations in the process.

Nalco Service Program
Our experienced local Nalco team will provide regular service for the program. Our service program will be tailored to your needs and may include:

- A Nalco representative in the mill
- On call coverage 24 hours, 7 days a week.
- Regular maintenance and repair of the feed and monitoring equipment.
- Bi-weekly reports summarizing program performance
- Weekly machine inspection for MB deposits with more detailed inspection during outages.
- System trouble shooting as required.

We look forward to discussing the value Nalco's OxiPRO™ Deposit Control Program can give [redacted] We want to thank you for the opportunity to service your facility and your request for this proposal.

Questions on Nalco OxiPRO System

1. What are the reactions that create the active ingredient?

   The stabilizers in the OxiPRO system when mixed with bleach in a specified ratio form a unique stabilized chlorine intermediate prior to being introduced to the paper making process. The stabilized chlorine intermediate ensures that the chlorine is not consumed by the organic components of the papermaking process such as fiber, and filler. This increases the opportunity for the stabilized intermediate to come in contact with planktonic bacteria or bacteria in a biofilm and then hydrolyze the chlorine back to hypochlorous acid --the biocide.

2. What is the mechanism of disinfection?

   Disinfection is completed through the action of hypochlorous acid on bacterial membranes, and oxidation of sulfhydryl groups.

3. What species of chlorine are present?

Hypochlorous acid is present in the beginning and the end of the stabilization process.

4. What are the by-products.(Spent Waste Products) ?

Sulfate in the case of 60620, Hydantoin in the case of 03PO125, minor organic salt in the case of 60615

5. What are the health hazards of the active ingredient.?

The active ingredient is hypochlorous acid (HOCl). The health hazards of HOCl are well known an documented.

EXHIBIT D

PM[redacted] Biocide Trial Operator Overview

[redacted]

[redacted]

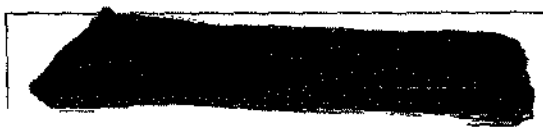
[redacted]

Presentation Outline

- Why are we running this trial?
- Why did we chose this program?
- Trial Plan details
- Logistics
- Most Important - Safety

Why are we running this trial?

- **Opportunity to Improve Operations:**
  - Cleaner water system
  - Fewer sheet breaks, defects, and rejects
  - Reduced downtime
  - Increased machine speed
- **Bottom line:**
  - Increase safety if the program can eliminate boilouts
  - Increase machine efficiency if reduce downtime
  - Better quality of less holes, defects and sheet breaks.



Why did we chose this program?

- Meets our goals
- Better monitoring tools
- New chemical technology with OxiPRO
- Direct comparison with other programs:
  - Boilouts only
  - Stabilized Chlorine – OxiPRO
  - DBNPA

[redacted]

Current Program

What are our goals for a biocide program:

- Safety
- No wet end deposits or breaks related to microbiological
- No sheet quality issues
- No boilouts/Wash-ups/Headbox deposits
- No impact on other chemistries

Current Microbiological Program:

- Current biocide program doesn't attack slime formers on [redacted] and [redacted] and no program on [redacted]. Using Bleach & DBNPA.
- Monitoring with weekly plate counts and ORP
- Boilouts when problem occurs
- Other
  - pH and temp range is good for filamentous and slime formers
  - Lower free chlorine in mill fresh water (<.5ppm)

Trial will help determine the Program to meet our goals on PM5

- Better data analysis = better decisions & optimization.

[redacted]

Better Monitoring

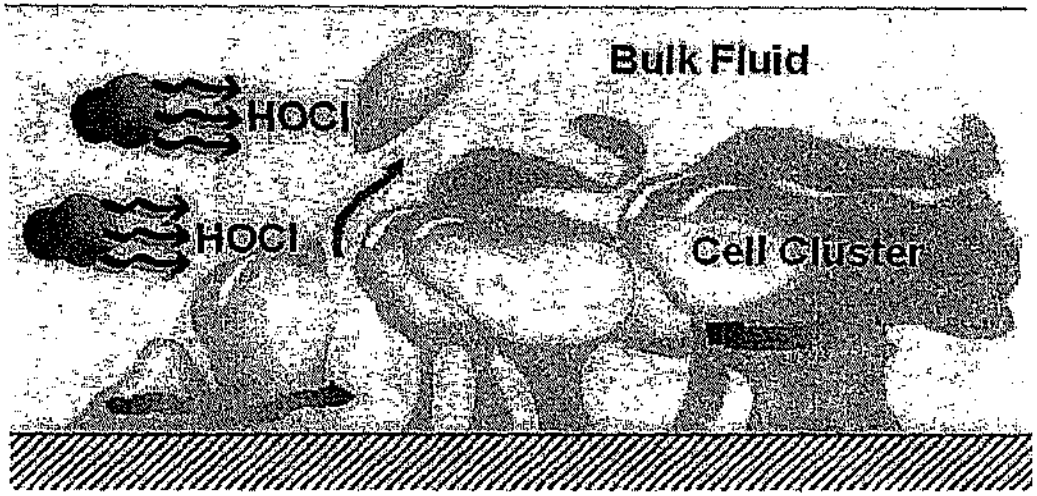
- Current Monitoring
  - Manual sampling
  - No formal program
  - Time lag for data
  - Reactive to problems on the machine
  - Plate counts and ORP only
- Monitoring during Trial
  - Automated and Manual sampling
  - Formal monitoring program
  - Real time data for biofouling and ORP
  - Ability to be Proactive to prevent problems
  - Alarm if problems occur

[redacted]

Biofilm Control

Situation without Stabilization

The free chlorine is lost by reacting with the surface of the biofilm.

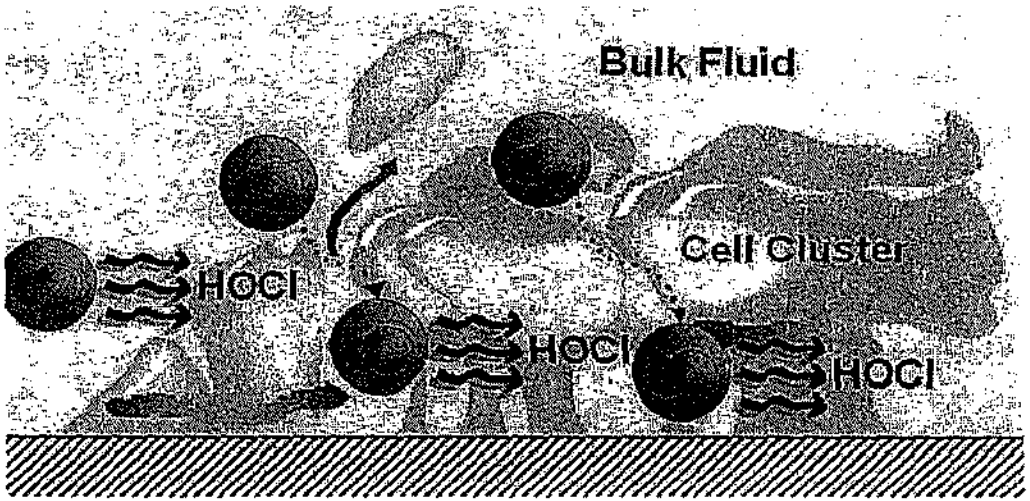


Stabilizer

NaOCl

Situation with Stabilization

The chlorine is released inside the biofilm matrix.

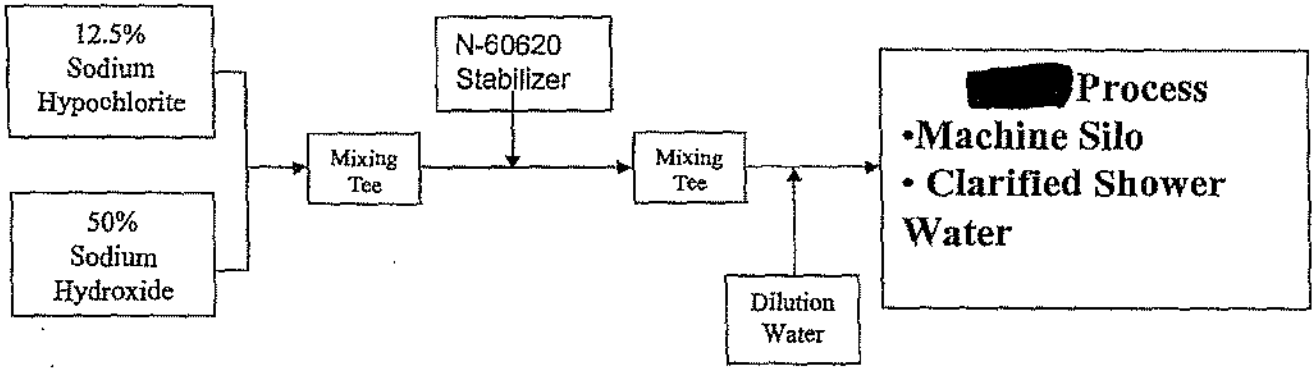


Trial Plan Details

- Timeline:
  - June 24 - Monitoring Only (Boilouts)
  - Aug / Sept - OxiPRO (2 months)
  - Oct / Nov - DBNPA (2 months)
- Feed Strategy and Application

[redacted]

Feed Strategy and Application



OxiPRO Location and Estimated Dose

- Machine Silo (Based on 65,000 gal, 12 ppm as total chlorine)
  - 65 GPD 60620, 38 GPD Mill Bleach
  - 45 min slugs, 4 times per day
  - Eliminate headbox and approach system biological deposition

- Shower Water Chest (Based on 40,000 gal, 10 ppm as total chlorine)
  - 5 GPD 60620, 2.5 GPD Mill Bleach
  - 10 min slugs, once per day
  - Provide kill and preservative for shower water and mist areas

[redacted]

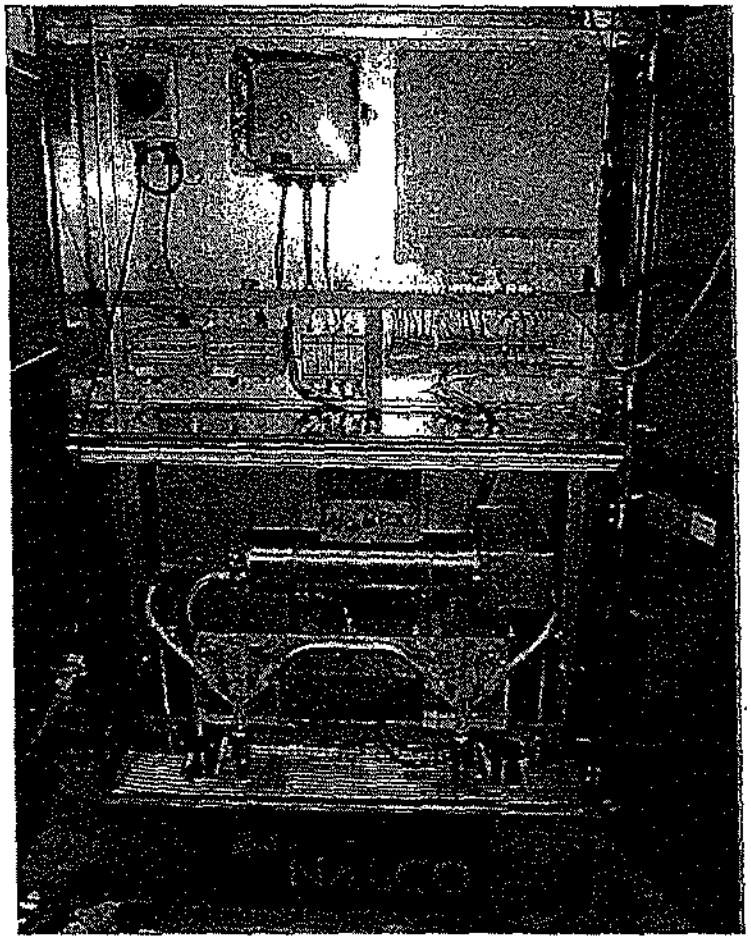
Logistics

- Locations of the chemicals and feed system
  - Temporary trial set up
    - In the basement, by pressure weir
    - Move existing totes to other locations
  - Long term plans
    - Hard piped to existing systems

- Monitoring system details
- Feed system details
- Component of the feed system

[redacted]

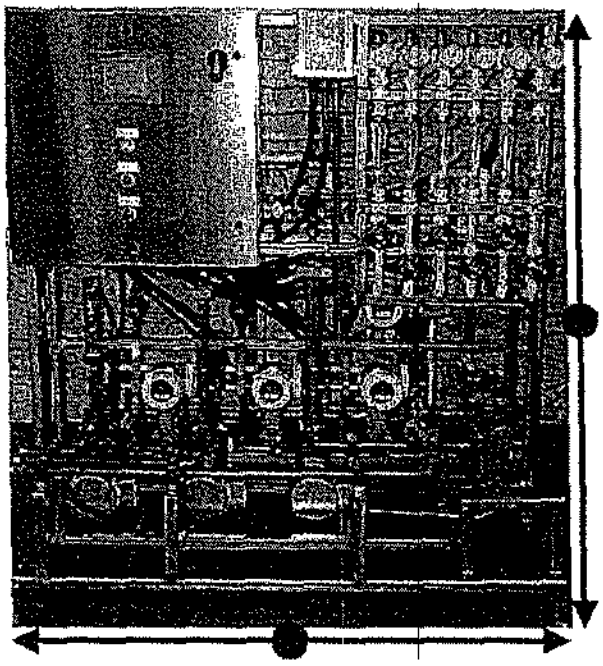
OxiPRO Monitoring



[redacted]

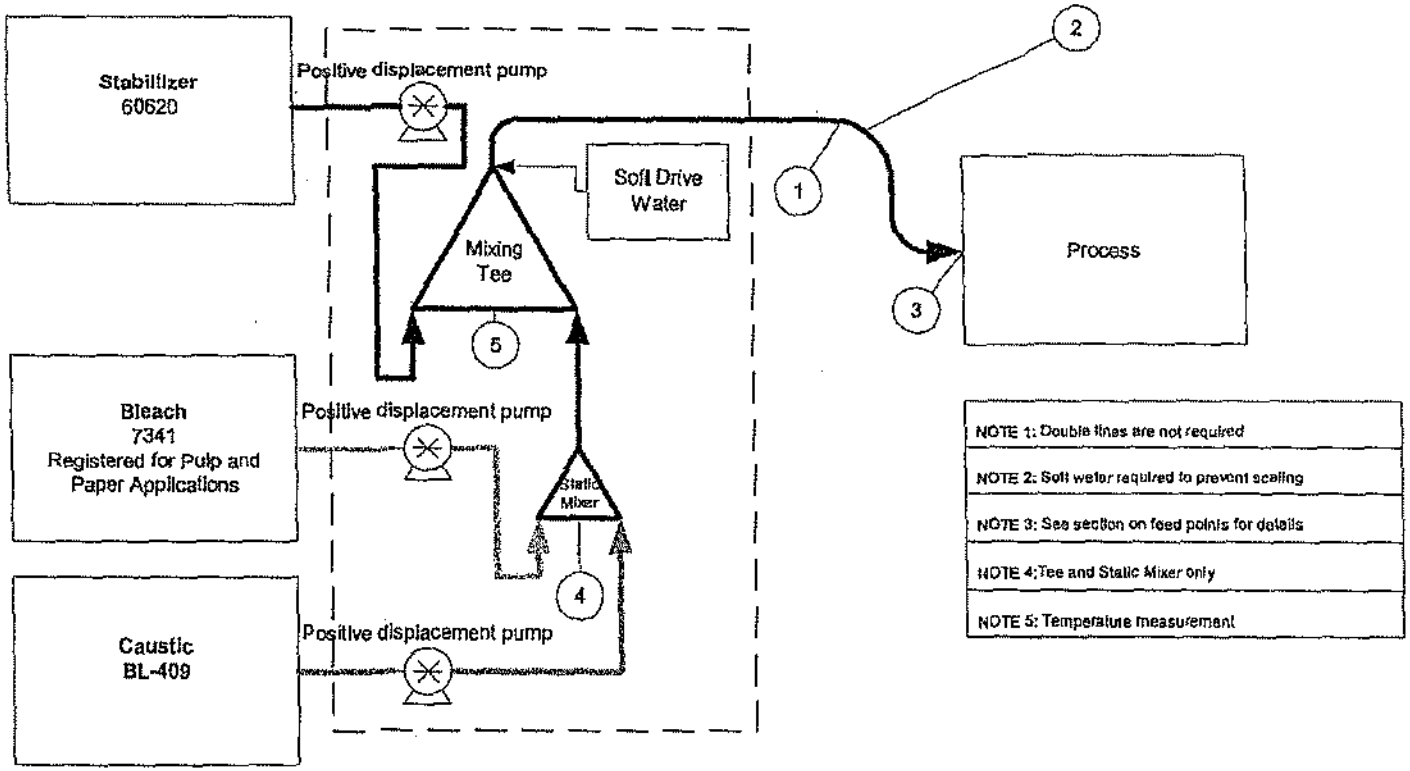
OxiPRO™ Feed System

- Fully automated to ensure safety and quality of product
- DCS connections available
  - Start/stop, flow rates, interlocks, etc
- Push water tie in, automatic flush water sequence
- All mixing and splitting done on skid
- Temperature monitoring to ensure proper ratios and safety
- Ability to shut down one addition point while running other(s)
- Nalco owned and maintained



3 Component with Drive Water

Basic Configuration: 3 Component with drive water



Safety

- Chemical hazards review
- Loading and unloading safety
  - Temporary operations SOP to refill totes
  - Long term – hard piped
  - Nalco rep to handle refills, PM [redacted] operator to truck totes
  - SOP review
- Feed system safety
  - Temporary piping (tube in tube)
- Other safety concerns

EXHIBIT E

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 15 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Carl Watson, Ph.D.
Sr. Regulatory Toxicologist
Buckman Laboratories, Inc.
1256 N. McLean Blv.
Memphis, TN 38108

Subject: **Busan 1215**
EPA Registration Number 1448-433
Application Dated June 6, 2007
Received Date June 11, 2007

Dear Mr. Watson:

The following label revisions submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Labeling:

O New Use: Industrial water systems

General Comment:

Should you have any questions concerning this letter please contact Drusilla Copeland at (703) 308-6224 or Velma Noble (70) 308-6233

Sincerely,

Velma Nobel
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Stamped Label

BUSAN 1215

BUSAN is a registered trademark.

A microbiocide for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products and in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

ACTIVE INGREDIENT(S)	
Ammonia (total)	7.59%
INERT INGREDIENTS	92.41%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
If Swallowed	- Call poison control center or doctor immediately for treatment advice. - Have person sip a glass of water, if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If Inhaled	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-278-0330 or 1-800-BUCKMAN for emergency medical treatment information.	

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wear protective eye-wear (goggles, face shield or safety glasses), impervious chemical-resistant gloves, and full body clothing (long sleeved shirt and long pants), socks and shoes when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

ACCEPTED

JUL 15 2008

Under The Federal Insecticide, Fungicide and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 1448-433

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PULP AND PAPER MILLS: BUSAN 1215 is used as a microbiocide in the manufacture of paper and paperboard that contacts food.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, BUSAN 1215 to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% w/wt). To insure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% w/wt). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

For continuous treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% w/wt). Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

INDUSTRIAL WATER SYSTEMS: BUSAN 1215 is used for the control of algal, bacterial and fungal deposits in industrial cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, industrial fresh water systems, airwashers, seawater desalination and reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes, sewage and wastewater systems. This product is also used for the control of algae, bacteria, fungi and mollusks in both seawater and freshwater influent systems.

When this product is used to treat sewage and wastewater systems, seawater, and freshwater influent systems for once-through industrial water systems, and seawater desalination and reverse osmosis systems, and the system water is not sent to a POTW; residual levels of chloramine in the effluent must be monitored and neutralized using on-line monitoring and control equipment.

When this product is used to treat recirculating cooling water systems, evaporative condensers, influent water systems (not part of once-through industrial water systems), brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes; effluent detection of chloramine should be conducted at least once per shift. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, BUSAN 1215 to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% w/wt). To insure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water process through a closed metered chemical feed system. The system operator must be trained by a Buckman representative in the use of the chemical feed system. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% w/wt). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

For continuous treatment, mix 0.5 fluid ounces of BUSAN 1215 to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% w/wt). Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the water being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources. .

CONTAINER DISPOSAL

PLASTIC: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

METAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Manufactured by

Buckman Laboratories, Inc.

1256 North McLean Blvd.
Memphis, Tennessee 38108, USA

(901) 278-0330 or 1-800-BUCKMAN

EPA Est. No.	1448-TN-1
EPA Reg. No.	1448-433
Product Weight	9.59 lbs/gal 1.15kg/l

Net contents are marked on the container.

HMIS / NPCA Ratings

Health 1 Flammability 1 Reactivity 0

Last Revision 7/17/2008

EXHIBIT F

Busan 1215 Feed System

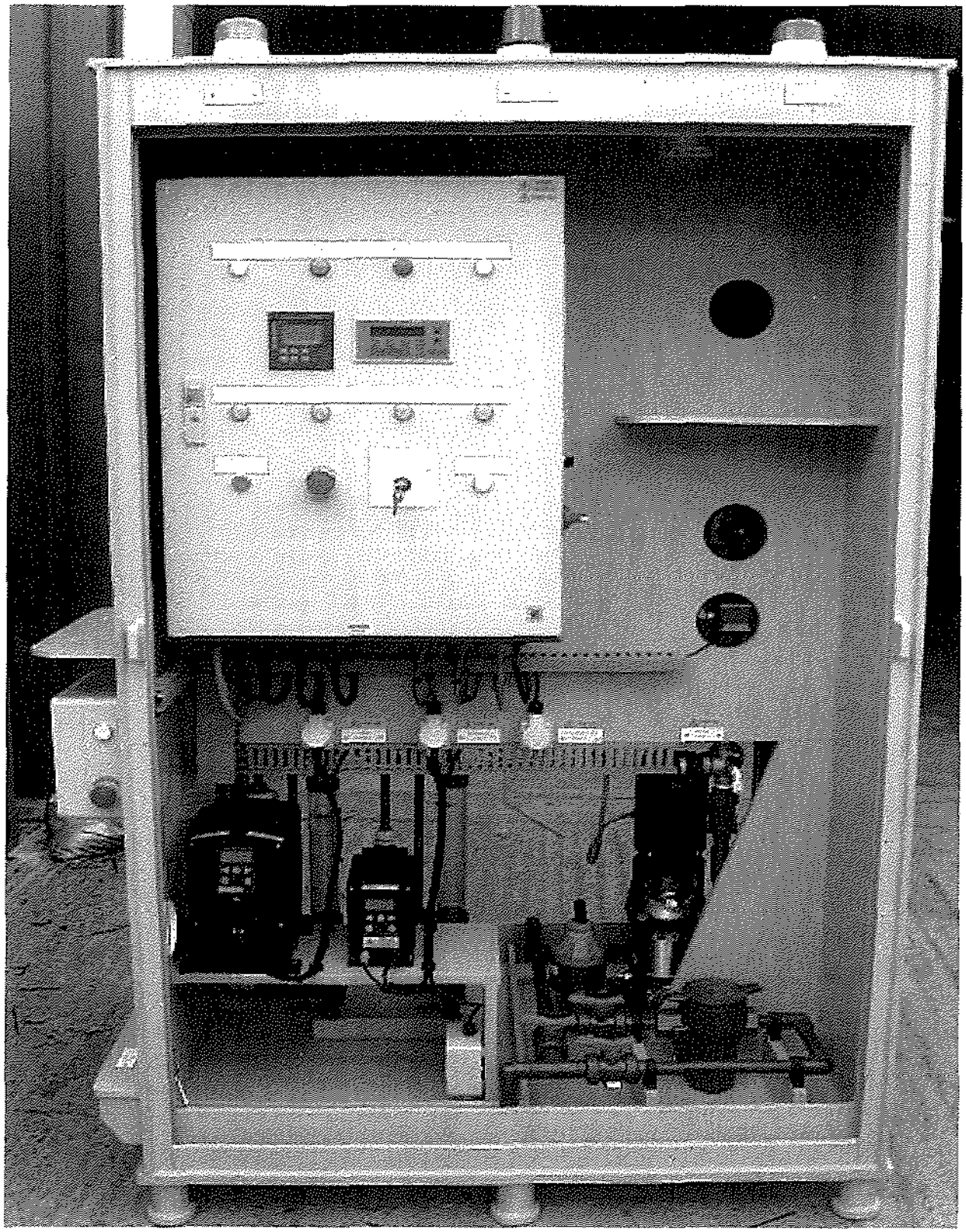
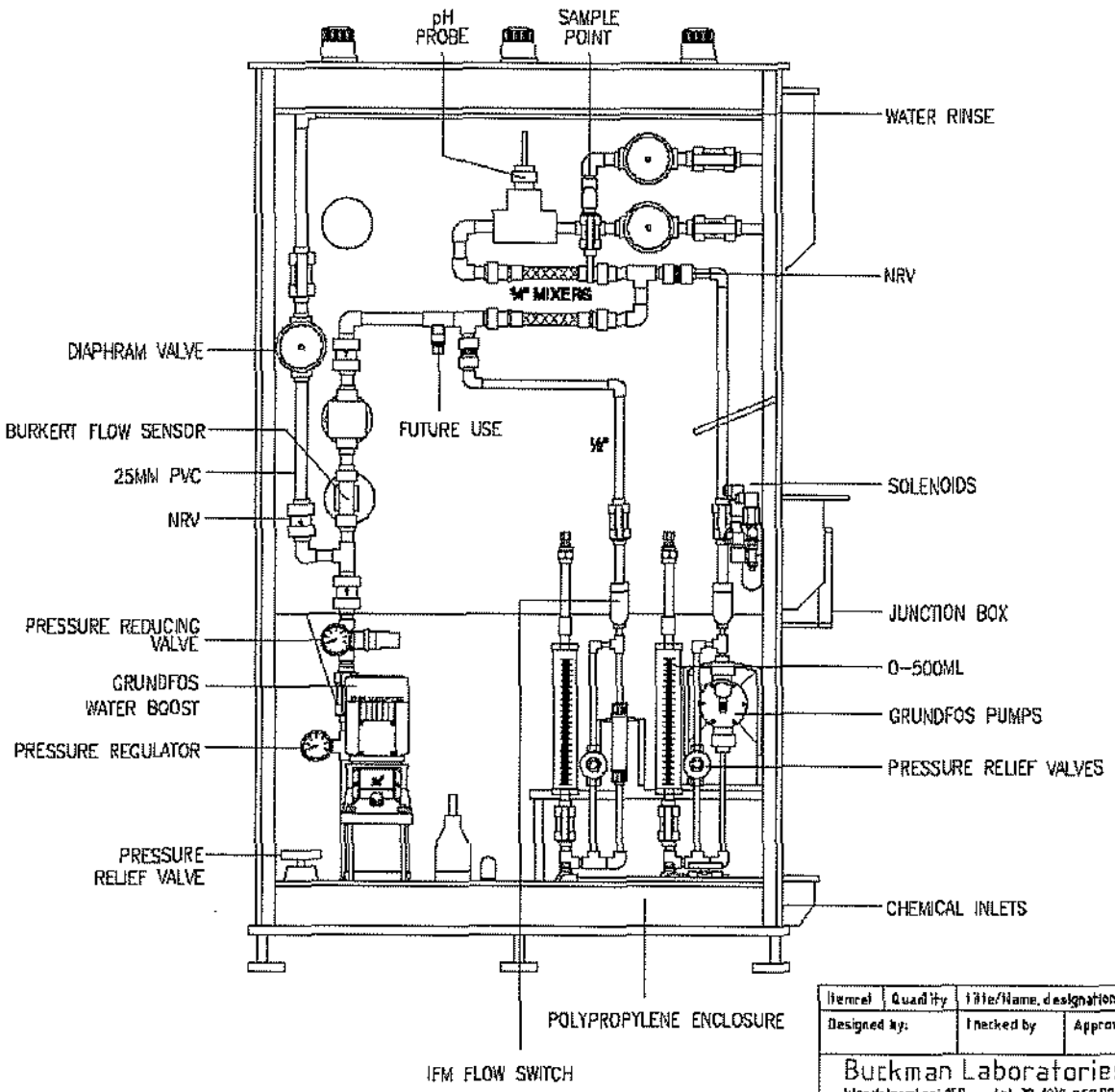


EXHIBIT G



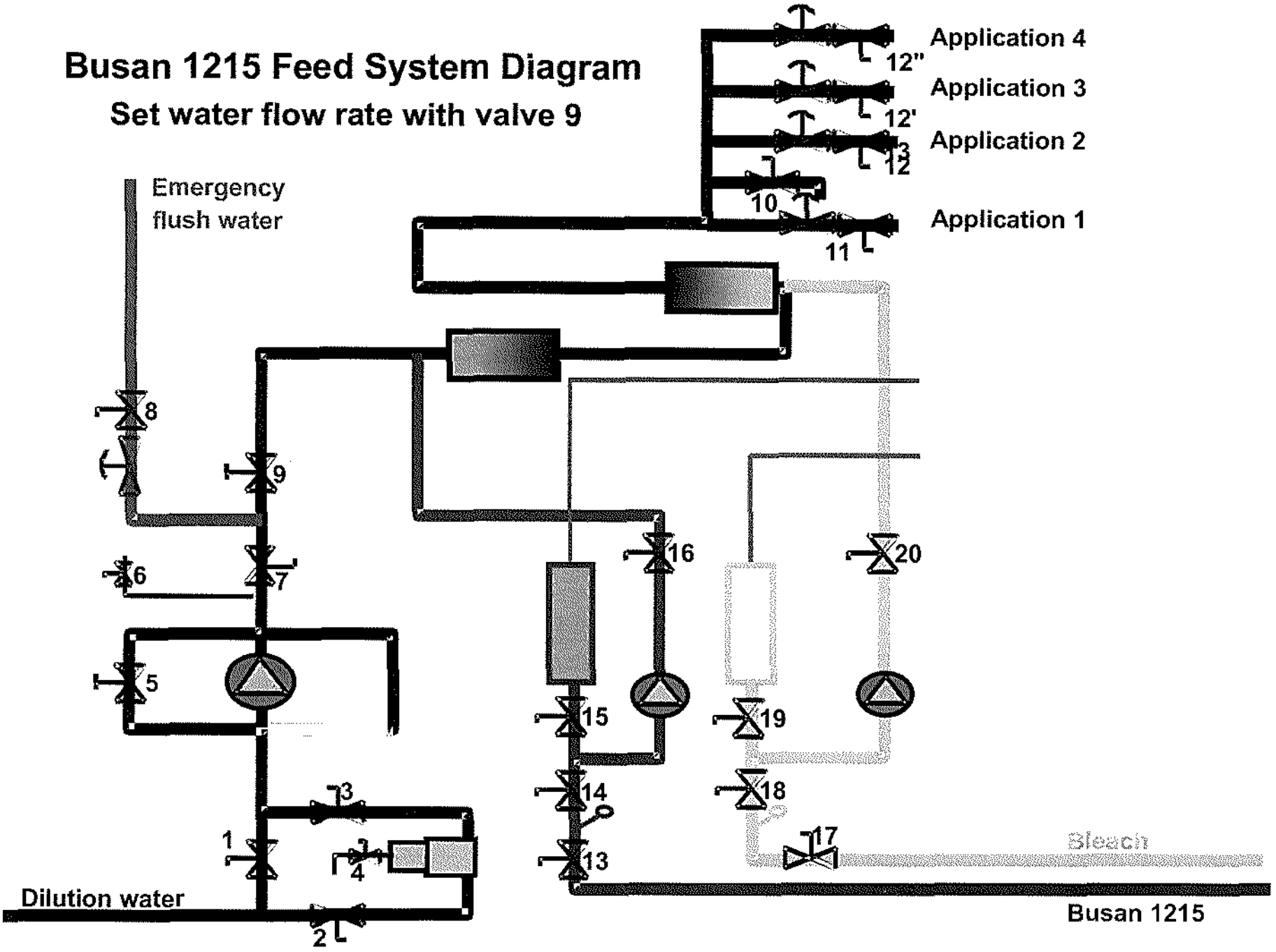
Item nr	Quantity	Title/Name, designation, material, dimension etc			Article No./Reference	
Designed by:		Checked by	Approved by – date	File name: EB05866GA	Date: 29/07/2005	Scale: NTS

Buckman Laboratories
Wandelgemkaai 159
B-9000 Gent
Belgie
Tel: 32-(0)9-257.92.11
Fax: 32-(0)9-257.93.08

BUSAN 1215 DOSING SYSTEM

NR.00.00.01 | Edition: REV 1 | Sheet: 2 of 3

EXHIBIT H


Busan 1215 Feed System Diagram
Set water flow rate with valve 9
Application 4
Application 3
Application 2
Application 1
12"
12'
12
10
11
Emergency
flush water
8
9
6
7
5
16
20
15
19
14
18
17
3
1
4
2
13
Bleach
Dilution water
Busan 1215

BUSAN 1215 Valve Settings		
#	*description*	*start position*
1	water filter bypass	closed
2	water filter inlet	open
3	water filter outlet	open
4	water filter drain	closed
5	water booster pump bypass	closed
6	dilution water drain sample tap	closed
7	dilution water supply	open
8	emergency flush supply	open
9	dilution water flow rate adjustment	open
10	sample tap Busan mixture to applications	closed
11	application point 1 outlet	open
12	application point 2, 3, 4 outlet	open
13	Busan 1215 inlet	open
14	Busan 1215 strainer isolation valve	open
15	Busan 1215 calibration column inlet	closed
16	Busan 1215 outlet	open
17	Bleach inlet	open
18	Bleach strainer isolation valve	open
19	Bleach calibration column inlet	closed
20	Bleach 1215 outlet	open

EXHIBIT I

OPP-2002-0162-0170

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 24, 2002

MEMORANDUM

FROM: Kathryn Boyle, CoChair IIFG

and

Kerry Leifer, CoChair IIFG

TO: Robert Forrest, Chief
Minor Use, Inerts, and Emergency Response Branch

SUBJECT: IIFG Decision Documents on Reassessing Exemptions from the Requirement of a Tolerance for the Mineral Acids (Hydrochloric, Carbonic, Phosphoric, and Sulfuric) and their Ammonium, Calcium, Ferrous, Ferric, Magnesium, Potassium, Sodium, and/or Zinc Salts

Collectively these Decision Documents cover four mineral acids and the salts of these acids. The individual Decision Documents are: (1) Hydrochloric Acid and Salts, (2) Salts of Carbonic Acid, (3) Phosphoric Acid and Salts, and (4) Sulfuric Acid and Salts. The Inert Ingredient Focus Group reassessment is based on various conclusions of the FAO/WHO Joint Expert Committee on Food Additives, conclusions of various FDA GRAS (Generally Recognized As Safe) Assessments, information previously used by OPP as part of the reregistration process, and other information available on government websites.

In total 46 exemptions from the requirement of a tolerance in 40 CFR 180 are reassessed. This total consists of 18 in the phosphoric acid document, nine in the hydrochloric acid document, six in the carbonic acid document, and 13 in the sulfuric acid document.

1 of 77

INERT INGREDIENT FOCUS GROUP

DECISION DOCUMENT for

Hydrochloric Acid and Salts

Petition No.: no

Tolerance Reassessments?: yes

Chemical Category/Group: mineral acid and salts

The following describes the various ways that hydrochloric acid and its salts are used.

Table 1: Use Pattern (pesticidal - inert ingredient)

Chemical Name	PC Code	40 CFR 180.1001	Inert Use Pattern (Pesticidal)	Current Inert List
hydrochloric acid	045901 845901	(c)	solvent, neutralizer	3
ammonium chloride	900327	(c)	intensifer, fire suppressant	4B
calcium chloride	875605	(c), (e)	stabilizer	4B
ferric chloride	834901	(d)	limitation of 2%, suspending, dispersing agent	4B
magnesium chloride	013902 813902	(c)	safener	4B
potassium chloride	813904	(c)	solid diluent, carrier	4B
sodium chloride	800012	(c)	solid diluent, carrier	4A

There is also a tolerance exemption for sodium chloride in 40 CFR 180.2.

Use Pattern: (pesticidal - active ingredient)

At this time, only hydrochloric acid and magnesium chloride are used as active ingredients. Hydrochloric acid is used as a disinfectant in 48 products. Many of these products are toilet bowl cleaners, with concentrations of hydrochloric acid ranging from 9.5 to 60%.

2077

However, potable human drinking water systems, meat and poultry processing plants, and hospitals are also use sites. Magnesium chloride is used as an herbicide at iceplants in only one product. There are no longer any EPA-registered active ingredient uses for any of the other above-listed chloride salts.

Table 2: Use Pattern (FDA GRAS)

Chemical	GRAS Citation	GRAS Uses
hydrochloric acid	21 CFR 182.1057	neutralizing agent
ammonium chloride	21 CFR 184.1138	dough strengthener, flavor enhancer, leavening agent, processing aid
calcium chloride	21 CFR 184.1193	anticaking agent, antimicrobial agent, curing or pickling agent, firming agent, flavor enhancer, humectant, nutrient supplement, pH control agent, processing aid, stabilizer and thickener, surface-active agent, synergist, texturizer
ferric chloride	21 CFR 184.1297	flavoring agent
magnesium chloride	21 CFR 184.1426	flavoring agent and adjuvant, nutrient supplement
potassium chloride	21 CFR 184.1622	flavor enhancer, flavoring agent, nutrient supplement, pH control agent, stabilizer or thickener

Ammonium chloride and calcium chloride also have uses in food contact surface sanitizing solutions under 21 CFR 178.1010.

Table 3: Use Pattern (non-pesticidal):

Chemical	Uses
hydrochloric acid	in the production of chlorides; refining ore in the production of tin and tantalum; to neutralize basic systems; laboratory reagent; hydrolyzing of starch and proteins in the preparation of various food products; pickling and cleaning of metal products; as catalyst and solvent in organic synthesis; for oil- and gas-well treatment; in removing scale from boilers and heat-exchange equipment; pharmaceutic aid (acidifier).
ammonium chloride	solutions for eye irrigation, **fertilizer**, dyeing, electroplating, safety explosives, lustering cotton, washing powders, electrolyte for dry cell batteries, soldering, metal and refinishing flux, galvanizing
calcium chloride	used for antifreeze and refrigerating solution, in fire extinguishers, to preserve wood and stone, ice manufacturing, glues, cements, fireproofing fabrics, automobile antifreeze mixtures, to melt ice and snow, as coagulant in rubber manufacturing, as size in admixture with starch paste, in concrete mixes to give quicker initial set and greater strength, freezeproofing of coal and ores, dust control on unpaved roads, sizing and finishing cotton fabrics, as brine for filling inflatable tires on tractors to increase traction.
ferric chloride	treatment of sewage and industrial wastes; etching agent for engraving, photography, and printed circuitry; condensation catalyst in Friedel-crafts reactions; mordant; oxidizing, chlorinating, and condensing agent; disinfectant; pigment; feed additive; water purification.
magnesium chloride	source of magnesium metal, chemical intermediate for magnesium oxychloride for cement, catalyst, flocculating agent, agent in fire extinguishers, agent in textile and paper manufacturing, component for ceramics, fireproofing agent for wood, component of refrigerating brines
potassium chloride	**fertilizer** component (primary plant nutrient); chemical intermediate in production of other potassium salts; photography; medical uses both orally and intravenously for treating potassium depletion states; dietary supplement.
sodium chloride	In the production of chemicals (sodium hydroxide, soda ash, hydrogen chloride, chlorine, metallic sodium), ceramic glazes, metallurgy, curing hides, food preservative, food seasoning, mineral waters, soap manufacture (salting out), home water softeners, highway deicing, regeneration of ion-exchange resins, photography, herbicide, fire extinguishing, nuclear reactors, mouthwash, medicine (heat exhaustion - intravenous solutions for fluid replacement), saline solutions for eye washes and contact lens solutions, salting out dyestuffs, supercooled solutions.

It should be noted that ammonium chloride and potassium chloride have uses as fertilizers. Plants need various elements (metals and non-metals) for proper growth. Especially for agricultural crops, plants are supplied these elements as part of chemical fertilizers. The most important elements for plant growth are nitrogen, phosphorus, and potassium. Other metals needed in the soil for plant up-take are calcium, magnesium, iron, and trace elements such as zinc. Both potassium chloride and ammonium chloride are intentionally added to growing agricultural crops as needed to promote plant growth.

4077

Assessment of Hydrochloric Acid and its Salts

Hydrochloric acid and its ammonium, sodium, potassium, calcium, magnesium, and iron salts are being assessed as a group due to their chemical similarities. Due to its acidic nature the toxicity of hydrochloric acid will be different from those of the more neutral chloride salts. However, the chloride salts all contain the chloride ion and thus share some common chemistries. A major focus of this assessment is the work previously performed by FDA in assessing the safety of these chemicals as food additives.

1. Physical/Chemical Properties:

The physical and chemical properties of hydrochloric acid and its various salts are described in the May 7, 2002 EFED Assessment. See attached.

2. Information Sources:

The following information was used in performing this assessment. The available information consisted of information retrieved from various websites, such as:

- EPA (www.epa.gov),
- NIOSH, (www.cdc.gov/niosh/ipcsneng/neng1184.html), (www.cdc.gov/niosh/ipcsneng/neng1051.html), (www.cdc.gov/niosh/ipcsneng/neng0764.html), (www.cdc.gov/niosh/npg/npgd0229.html), and (www.cdc.gov/niosh/npg/npgd0346.html)
- TOXNET (www.toxnet.nlm.nih.gov.),
- WHO (www.inchem.org/documents/jecfa/jecmono/v05je83.htm) and (www.inchem.org/documents/jecfa/jecmono/40abcj43.htm)

Various FDA GRAS Assessments were used, as well as, the FAO/WHO Assessments.

3. NIOSH (National Institute for Occupational Safety and Health)

The NIOSH Pocket Guide for hydrogen chloride indicates that hydrogen chloride is a colorless to slightly yellow gas with a pungent, irritating odor. It is nonflammable. Additional information on the NIOSH web-site included the Occupational Health Guideline for Hydrogen Chloride. Hydrogen chloride gas irritates the eyes, mucous membranes, and skin. The current OSHA standard for hydrogen chloride is a ceiling of 7 mg/m^3. Ingestion of hydrochloric acid can cause severe burns of the mucous membranes of the mouth, esophagus, and stomach.

The NIOSH International Chemical Safety Cards for magnesium and calcium chloride indicate that TLVs (Threshold Limit Values) have not been established. Both chemicals can irritate the skin and the respiratory tract, and when dissolved in water liberate a considerable

5877

amount of heat.

According the International Chemical Safety Card for ammonium chloride, the substance irritates the eyes, the skin and the respiratory tract. The TLV is established only for the fume.

The NIOSH International Chemical Safety Cards for iron salts (soluble, as Fe) which includes ferric chloride indicates an exposure limit of 1 mg/m^3 (time weighted average).

4. Acid Characteristics

An acid is a substance that when dissolved in water yields H^+ ions. The increase of the concentration of the H^+ ions lowers the pH. Mineral acids contain a non-metal such as phosphorus, nitrogen, sulfur, or chlorine which may or may not be combined with oxygen. When combined with oxygen, these anions can be referred to as oxyanions. Strong acids are those acids that when dissolved completely transfer their H^+ ions to water. Hydrochloric acid is an example of a strong acid.

5. Cations: Sodium, Potassium, Calcium, Magnesium, and Iron

Generally, a salt of a strong acid, such as hydrochloric acid, when dissolved in water dissociates to yield the chloride ion (an anion, which is negatively charged) and a positively charged cation. In the human body, these salts tend to dissociate and thus, for the most part, react in the body as the anion and the cation.

Metals such as calcium, sodium, magnesium, potassium, and iron are also required for proper functioning of human biological systems. For risk assessment purposes an important feature of these metals is that overall the body does have an effective means of processing them. The primary means of exposure to these cations is ingestion. Four of the most common cations required for functioning of human biology are: sodium, potassium, calcium and magnesium. Chemically, sodium and potassium belong to the same chemical family: calcium and magnesium belong to a different chemical family.

Sodium:

The average human body burden of sodium is approximately 20 grams (g) for a 70 kilogram (kg) adult. The sodium cation is necessary for the nerves and muscles to function properly. It is the principal cation of extracellular fluid, and helps to maintain the body's water balance. These electrolytes, the electrically charged ions in the body fluids, consist to a great extent of sodium and potassium. There is no Recommended Dietary Allowance (RDA) for sodium.

Potassium:

The average human body burden of potassium is approximately 140 g for a 70 kg adult. The potassium cation is important in regulating blood pressure, regulating cellular water content, maintaining proper pH balance, and transmission of nerve impulses. It helps to regulate the electrical activity of the heart and muscles. The potassium RDA is 900 mg/day.

Calcium:

The average human body burden of calcium is approximately 1 kg for a 70 kg adult; or 1/70th of our weight is calcium. The calcium cation is necessary for bone and teeth formation. It is also important for the proper functioning of nerves, enzymes, and muscles, and plays a role in blood clotting and the maintenance of cell membranes. The RDAs for calcium are 1000 mg/day for adults aged 19 to 50 years and 1200 mg/day for individuals older than 50 years.

Magnesium:

The average human body burden of magnesium is approximately 20 g for a 70 kg adult. The magnesium cation is also used in building bones. It plays a role in releasing energy from muscles and regulating body temperature. The RDA for magnesium is 310 to 320 mg/day for adult females and 400 to 420 mg/day for adult males with the RDA increasing with increasing age.

Iron:

Another common metal cation that is needed for functioning of human biology, but in smaller amounts often referred to as trace, is iron. The human body burden of iron is approximately 4.1 g for a 70 kg adult. Iron functions as a carrier of oxygen. The hemoglobin molecule in blood transports oxygen from the lungs to the cells. The myoglobin molecule supplies oxygen to muscle cells. Iron deficiency is characterized by anemia, stunted growth, fatigue, and lowered resistance to infection. The RDAs for iron are 10 mg/day [0.14 mg/kg/day for an adult (70 kg) male (25 to 50 years)] and 15 mg/day [0.25 for an adult (60 kg) female (19 to 50 years)]. Pregnant and nursing woman have increased requirements for iron.

Dietary iron is poorly absorbed. The intestinal mucosa is a limiting factor in iron absorption. Normal absorption is about 1 mg/day in an adult male, and about 1.4 mg/day in an adult female. Absorption occurs in the divalent (ferrous) form, which must then be oxidized to the trivalent (ferric) form for use. Acute toxicity of iron ingested from normal dietary sources has not been reported. However, death especially in young children has resulted from ingestion of large overdoses of medicinal iron. (doses ranging from 40 to 1600 mg/kg - average 900 mg/kg). It is noted that the iron from ferric salts is less well absorbed than that from ferrous salts.

6. Ammonium Salt:

Ammonium chloride dissociates to the chloride anion and the positively charged ammonium cation (NH_4^+). Humans cannot convert atmospheric nitrogen to any form that can be used as part of any of the various metabolic cycles. Therefore, reduced nitrogen (NH_4^+) has to enter the body from an outside source. These sources are the nitrogen-containing amino acids in protein which are consumed daily as part of the diet. Although the human body can produce some amino acids, ten amino acids are considered "essential" amino acids, i.e., they must be consumed in the diet.

Generally the body works to maintain a balance of nitrogen intake and nitrogen excretion. The estimated daily ammonia intake through food and drinking water is 18 mg. In contrast, 4000 mg of ammonia per day are produced endogenously in the human intestine.

Ammonia and the ammonium ion are integral components of normal human metabolic processes. Ammonia is released following deamination that occurs when protein is used by the body for energy production. The liver converts ammonia via the urea cycle into urea. According to FDA in the "Evaluation of the Health Aspects of Certain Ammonium Salts as Food Ingredients" (1974), "the normal liver so readily detoxifies ammonium ion from alimentary sources that blood concentrations of ammonium salts do not rise to the levels necessary to evoke toxic response." Approximately 80% of the body's excess nitrogen is eliminated through the kidneys as urea, approximately 25 to 30 grams per day.

8677

7. Toxicological Profile Table

With the exception of the information in IRIS (Integrated Risk Information System), the Agency has not reviewed any of the toxicological studies in the following table for hydrochloric acid or any of its salts. The reviews of these studies were obtained from Toxnet, as well as other government websites.

Table 4: Toxicological Profile

Chemical	Toxicity	Other Information
Hydrochloric Acid	Severely corrosive by all routes as 1N solution; IRIS RfC = 2 x 2^{-2} mg/m^3 based on hyperplasia of nasal mucosa, larynx and trachea in rat chronic inhalation study; LOAEL = 15 mg/m^3 (10ppm); Chemical has no systemic toxicity associated with exposure except the acute effects of corrosion/ irritation depending upon the pH of the solution.	CERCLA Reportable Quantity: greater than 10 lb (4.54 kg); Hazardous Air Pollutant (HAP) chemical; 1995 production 7.33 billion lbs;
Ammonium Chloride	Mild skin and respiratory system irritant; Dust irritating to eyes; Ingestion of 40 to 50 g over a short period would be expected to exhaust available body buffers of the average adult and produce potentially fatal acidosis. Mild acidosis occurs at a dose of 2 g; One sixth molar ammonium chloride was given to mice orally in the drinking water after day 7 during pregnancy and although the offspring were small sized no congenital defects were found; Absorbed almost 100% in the gastrointestinal tract	CERCLA Reportable Quantity: greater than 5000 lb (2270 kg);

Magnesium Chloride	Rat oral LD_{50} = 2800 mg/kg; signs: convulsions, changes in respiration and cardiac function; Drug use as electrolyte replenisher in hemadialysis and peritoneal dialysis fluid; Cathartic; 90-day study in rats with **magnesium chloride hexahydrate** - doses: 0, 0.1, 0.5, 2.5% in diet -NOAEL = 2.5% (highest dose tested (HDT)); Developmental study in rats with **magnesium chloride hexahydrate** -doses: 0, 200, 400, 800mg/kg/day NOAEL= 800mg/kg/day (HDT); Carcinogenicity study in mice with **magnesium** chloride **hexahydrate** -doses 0, 0.5, 2% in diet for 96 wks–not carcinogenic	Deliquescent US production 1972 8.6 x 10^{11} grams
Calcium Chloride	Rat oral LD_{50} = 1000 mg/kg; Mouse LD_{50} = 1940 mg/kg; Anhydrous form irritating to skin, eyes and mucus membranes	Hygroscopic; Liberates heat during water absorption and on dissolution; US production 1993 1.4 billion lbs
Ferric Chloride	Rat oral LD_{10} = 0.5-5 g/kg added to bottled water; Skin, eye and mucous membrane irritant; Carcinogenicity study in rats at doses of 0, 0.25, 0.5% in drinking water was negative; Excess ingestion of iron produces liver toxicity; Acute ingestion of 0.5 g of iron prodoces severe toxicity	Hygroscopic; CERCLA Reportable Quantity: greater than 100 lb (45.4 kg); US production 1.2 x 10^{11} grams; iron drinking water guideline 300 ug/L

Potassium Chloride	Rat oral LD_{50} = 2600 - 3020 mg/kg; Mild eye irritation for rabbits; Irritating to skin and mucous membranes; Commercial dietary salt substitute;	US production 1980 = 3 x 10^{12} grams; OSHA PEL = 15 mg/m^3, 5 mg/m^3 for respirable particles
Sodium Chloride	Skin, eye and mucous membrane irritant; Affects blood pressure in humans; Average daily intake of US citizens 10-12 g/day with 3 g occurring naturally, 3 g added in cooking, 4-6 g in processed foods	Common table salt, sea salt

8. OPP REDs (Reregistration Eligibility Decision Document)

Mineral Acid RED

The following information on the acute toxicity of hydrochloric acid was in the 1993 RED: The oral LD_{50} is 1000 mg/kg, toxicity category III. The dermal LD_{50} is > 2000 mg/kg, toxicity category III. Hydrochloric acid is toxicity category I for eye and dermal irritation. No other toxicological data were required based on the use patterns at the time of the RED and the corrosiveness shown in the acute studies for dermal and eye irritation.

Inorganic Halide RED

This 1993 RED included sodium chloride. The oral LD_{50} (rat) is 3000 mg/kg, toxicity category III. Sodium chloride was classified as moderate, toxicity category III for eye irritation, and mild, toxicity category IV for skin irritation. Because of its abundance in the environment and low toxicity to humans, no additional toxicity data were required.

9. FDA GRAS (Generally Recognized As Safe) Assessments

Hydrochloric Acid

The FDA Assessment is titled "Evaluation of the Health Aspects of Hydrochloric Acid as a Food Ingredient" (1979). Hydrochloric acid has a variety of FDA approvals for food additive use. "Food stuffs to which hydrochloric acid has been added expose consumers predominantly to chloride ions and other chemical products resulting from its reaction to chloride ions and other chemical products resulting from its reaction with neutralizing agents or chemicals in the food. Free hydrochloric acid would be expected to be present in only minute amounts, if at all."

The human stomach normally contains sufficient hydrochloric acid to maintain the pH of gastric juice at 1.5 to 2.5. The introduction of any hydrochloric acid into the stomach proportionally depresses the secretion of the acid by the stomach.

According to FDA:

> "Hydrochloric acid in concentrated form is a strongly corrosive agent and the consequences of exposure to it are well-known. However, as it is used in food processing, or as a food additive to adjust the pH, hydrochloric acid is neutralized or buffered by the food to which it is added. Thus, human consumption is not of the acid, but of the chloride ion in the salts formed in the neutralization process.....There is no evidence in the available information on hydrochloric acid that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current or that might reasonably be

expected in the future."

Ammonium Chloride

The FDA Assessment is titled "Evaluation of the Health Aspects of Certain Ammonium Salts as Food Ingredients" (1974).

> "Ammonia and ammonium ion are integral components of normal metabolic processes and play an essential role in the physiology of man. Although there have been no significant feeding studies specifically designed to ascertain the safety threshold of ammonium compounds as food ingredients, numerous metabolic studies have been reported in the scientific literature. Extrapolation of these findings to the concentrations of ammonium compounds normally present in foods does not suggest that there would be untoward effects at such levels."

Calcium Chloride

The FDA Assessment is titled "Evaluation of the Health Aspects of Certain Calcium Salts as Food Ingredients" (1975). The estimated per capita daily intake of calcium chloride is 160 mg. Both the calcium and the chloride are common constituents of food and are metabolized by the normal metabolic processes in humans.

Magnesium Chloride

The FDA Assessment is titled "Evaluation of the Health Aspects of Magnesium Salts as Food Ingredients" (1976). Magnesium is (1) a dietary essential, (2) involved in many metabolic reactions, (3) important in electrolyte balance, and (4) present in fruits, vegetables, grains, milk, meat and fish. No chronic toxicity data were available. The "status of magnesium as a ubiquitous and essential dietary ingredient for the maintenance of homeostatic and bioenergetic mechanisms leads to the opinion that none of the available evidence suggests any probable hazard when any of the GRAS compounds of magnesium is used as a food ingredient." The conclusion was reached that there was no available information on magnesium chloride to demonstrate, or suggest "reasonable grounds to suspect, a hazard to the public when ... used at levels that are now current and in the manner now practiced, or which might reasonably be expected in the future."

Potassium Chloride

The FDA Assessment is titled "Evaluation of the Health Aspects of Sodium Chloride and Potassium Chloride as Food Ingredients" (1979). The concentration of potassium in blood serum is maintained normally between 3.5 and 5 meq/L.

"The available evidence indicates that in normal individuals potassium chloride

is well tolerated, and that metabolism quickly and efficiently adjusts potassium in the body to narrow homeostatic levels. Certain health conditions are known to affect the normal homeostatic control of sodium and potassium in the body to narrow homeostatic levels. Certain health conditions are known to affect the normal homeostatic control of sodium and potassium metabolism, and patients with these conditions must adjust their diets to avoid proscribed electrolyte intakes. Water intake, efficiency of the kidney, and the ratio of sodium to potassium in the diet are interrelated factors that must be evaluated in considering the health aspects of changing the relative intakes of sodium chloride and potassium chloride."

It was concluded:

"There is no evidence in the available information on potassium chloride that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future."

Sodium Chloride

The FDA Assessment is titled "Evaluation of the Health Aspects of Sodium Chloride and Potassium Chloride as Food Ingredients" (1979). Sodium chloride, commonly known as table salt, occurs abundantly in nature, in sea water and mineral springs, and in large underground deposits. The mineral form is called halite. It is a food ingredient and has historically been considered an essential part of the diet. The body must have some sodium. The human body has a homoeostatic control to maintain the proper balance of sodium, potassium. and chlorine in the human body. The concentration of sodium in blood serum is maintained normally between 136 to 145 meq/L. That of chlorine is 96 to 106 meq/L.

The American diet is considered to contain an abundance of salt which if consumed in excess, may have adverse health consequences. In fact, treatment of certain diseases such as hypertension can require restriction of salt intake. Acute and chronic toxic effects, including death, can occur when salt is ingested in excessive amounts. There is no daily requirement for salt, as it would be a level highly dependent all dietary sources, the level of potassium and the sodium to potassium ratio in the diet, and health conditions such as sweating.

The Assessment considers that the consumption of sodium chloride in the aggregate should be lowered in the United States. The Assessment concluded: "The evidence on sodium chloride is insufficient to determine that the adverse effects reported are not deleterious to the health of a significant proportion of the public when it is used at levels that are now current and in the manner now practiced."

14877

10. FAO/WHO Expert Committee on Food Additives

WHO has performed two assessments: hydrochloric acid in 1966 and calcium acetate, chloride, gluconate, and sulfate in 1973.

Both assessments discussed that from a toxicological point of view, there were no concerns for the chloride ion. It was considered to be naturally-occurring and a normal participant of animal and human metabolism.

11. Human Health Hazard Characterization:

Hydrochloric acid in its concentrated form is highly corrosive. Due to this property toxicity testing can only be performed on dilute concentrations or on neutralized forms of the acid such as a salt. The consequences of acute exposure to hydrochloric acid are well-understood. Dermal exposure can lead to burns. Exposure to the gas can cause severe irritation of the upper respiratory tract.

Exposure to hydrochloric acid in pesticide products as an inert ingredient would be in the role of a pH adjuster. This is indicative of the use of small amounts of hydrochloric acid that are incorporated in a pesticide product to lower the pH . After the pH adjustment is performed, the hydrochloric acid would be neutralized. As an active ingredient hydrochloric acid is subject to FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) registration requirements and various labeling language as specified in the RED. Hydrochloric acid, whether used as an inert or an active ingredient, must be used and applied according to good manufacturing or good agricultural practices. However, there are no significant adverse effects, to the general public or any population subgroup from consumption of residues of hydrochloric acid resulting from pesticide product uses.

As a group salts of hydrochloric acid constitute a group of chemicals with many uses including direct use in the food supply. In particular sodium chloride, common table salt, can be purchased and used by the public in the amounts specifically chosen for their individual wants and desires. According to the information available to the Agency, sodium chloride used in food processing results in consumption of 4 to 6 grams of sodium chloride in the average diet per day. The average individual adds up to another 3 grams of sodium chloride during cooking and at the table.

The available toxicity data indicates that the human body metabolizes chloride, ammonium, calcium, iron, magnesium, potassium, and sodium ions through well-understood pathways. In fact, all are necessary human nutrients. Various salts of hydrochloric acid have been used in the food supply for a number of years. There are no available data to indicate any significant adverse effects to the general public or any population subgroup from consumption of residues of the ammonium, calcium, iron, magnesium, potassium, and sodium salts of

hydrochloric acid resulting from pesticide product uses.

Given the long history of safe use, the available toxicity data, an understanding of the human body's ability to metabolize these chemicals, and the evaluations by FDA and WHO, the IIFG believes that ammonium, sodium, potassium, magnesium, calcium and iron chloride are of low oral toxicity.

12. Type of Risk Assessment/Risk Characterization:

The toxicity of these chemicals derives from the irritation and caustic effects; therefore, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate.

Given the widespread occurrence of hydrochloric acid and its ammonium, calcium, iron, magnesium, potassium, and sodium salts in the existing food supply, the amounts that may be present in food as a result of the use of these chemicals in a pesticide product would not be expected to significantly increase the existing amounts in the food supply. There is no available information on any of the salts of hydrochloric acid considered in this document indicative of a human health hazard resulting from the EPA-regulated uses as well as the FDA GRAS uses to the general public or any population subgroup. No additional information are needed to assess the safety of hydrochloric acid and its salts.

13. Sensitivity of Infants and Children:

Due to its acidic nature, its corrosive potential, there is high acute toxicity for hydrochloric acid. Hydrochloric acid must be used in pesticide products according to good manufacturing or good agricultural practices. The ammonium, calcium, iron, magnesium, potassium, and sodium salts of hydrochloric acid have low toxic potential. At this time, there is no concern for potential sensitivity to infants and children. A safety factor analysis has not been used to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

14. Environmental Fate and Ecotoxicity Assessment/Characterization:

In general, the constituents of the mineral acids, such as hydrochloric acid, are commonly found in soil and water in the environment suggesting that releasing low levels of these chemicals would not normally be expected to adversely effect wildlife or water resources. Large releases may adversely affect wildlife and water resources either directly or indirectly. Direct effects may result from exceeding toxicity thresholds of specific chemicals. Indirect effects may be manifested through disrupting ecosystems through altering pH or increasing availability of algal nutrients.

Hydrochloric acid is a strong acid. The magnitude of the pH changes, and thus the magnitude of effects, would depend on a number of factors including the amount of material released and the buffering capacity of the exposed soil or water. Normal aquatic pHs range from 5 to 9. EPA's Office of Water recommended water quality criteria for pH are 6.5 to 9 for freshwater and 6.5 to 8.5 for saltwater. At higher or lower pH aquatic life is expected to be adversely impacted. In addition, rapid changes in pH can also be detrimental to aquatic life. Hydrochloric acid is not expected to be persistent in the environment. Instead it is expected to dissociate, react with organic or inorganic materials, and complex with ionic substrates.

Hydrochloric acid salts dissociate in water resulting in a positively charged (cationic) metal in solution. Dissociation is frequently dependent on pH, with lower (more acidic) pHs resulting in higher levels of dissociation and greater solubility. Aquatic toxicity of metals varies with the species of metal and its concentration. EPA's freshwater water quality criteria for iron is 1 ppm implying relatively low toxicity. Metals do not degrade and thus are permanent in the environment. They are likely to dissipate by being sequestered in soil, sediment, and plants.

15. Cumulative Exposure:

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide chemical's residues and "other substances that have a common mechanism of toxicity." The chemicals considered in this document are structurally related; however, all of the salts are low toxicity chemicals. Therefore, the resultant risks separately and/or combined should also be low. EPA does not have, at this time, available data to determine whether these pesticide chemicals have a common mechanism of toxicity with other substances or how to include these pesticide chemicals in a cumulative risk assessment.

16. Determination of Safety:

Based on its review and evaluation of the available information, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to residues of hydrochloric acid and its ammonium, sodium, potassium, calcium, magnesium, and iron salts. Therefore, the following exemptions from the requirement of a tolerance are reassessed: In 40 CFR 180.2 sodium chloride. In 40 CFR 180.1001 (c) ammonium chloride, calcium chloride, hydrochloric acid, magnesium chloride, potassium chloride, and sodium chloride. In 40 CFR 180.1001 (d) ferric chloride. In 40 CFR 180.1001 (e) calcium chloride.

17. List Reclassifications:

The following List reclassifications are made or confirmed:

Hydrochloric acid: List 4B. With the restriction of use as a solvent, pH adjuster, neutralizing agent.
Ammonium chloride: List 4B
Calcium chloride: List 4B
Ferric chloride: List 4B, current limitation remains in place.
Magnesium chloride: List 4B
Potassium chloride: List 4A considering its use as a salt substitute
Sodium chloride: List 4A considering its use as common table salt

The following table lists the various chemical names, CAS Reg. No., and CAS Index Names that will be used for listing in 40 CFR.180. Note that both the anhydrous and the hydrated forms are included. The Agency sees no reason to distinguish between these chemicals given that the only difference is the attachment of the water molecules.

Chemical Name	CAS Reg. No.	Chemical Abstracts Index Name
Hydrochloric acid	7647-01-0	Hydrochloric acid (6CI, 7CI, 8CI, 9CI)
Ammonium chloride	12125-02-9	Ammonium chloride ((NH4)Cl) (9CI)
Calcium chloride	10043-52-4	Calcium chloride (CaCl2) (9CI)
Calcium chloride hydrate (CaCl2.1/3H2O)	56073-24-6	Calcium chloride (CaCl2), hydrate (3:1) (9CI)
Calcium chloride, hydrate (8CI)	22691-02-7	Calcium chloride (CaCl2), hydrate (9CI)
Calcium chloride dihydrate	10035-04-8	Calcium chloride (CaCl2), dihydrate (9CI)
Calcium chloride hexahydrate	7774-34-7	Calcium chloride (CaCl2), hexahydrate (9CI)
Calcium chloride monohydrate	13477-29-7	Calcium chloride (CaCl2), monohydrate (9CI)
Ferric chloride	7705-08-0	Iron chloride (FeCl3) (8CI, 9CI)
Ferric chloride monohydrate	60684-13-1	Iron chloride (FeCl3), monohydrate (9CI)
Ferric chloride dihydrate	54862-84-9	Iron chloride (FeCl3), dihydrate (9CI)
Iron III chloride hexahydrate	10025-77-1	Iron chloride (FeCl3), hexahydrate
Ferric chloride dodecahydrate	58694-80-7	Iron chloride (FeCl3), dodecahydrate (9CI)
Ferric chloride nonahydrate	58694-79-4	Iron chloride (FeCl3), nonahydrate (9CI)
Ferric chloride sesquihydrate	115321-78-3	Iron chloride (FeCl3), hydrate (2:3) (9CI)
Ferric chloride trihydrate	58694-75-0	Iron chloride (FeCl3), trihydrate (9CI)
Magnesium chloride	7786-30-3	Magnesium chloride (MgCl2) (9CI)
Magnesium chloride hexahydrate	7791-18-6	Magnesium chloride (MgCl2), hexahydrate (9CI)

18 of 77

INERT INGREDIENT FOCUS GROUP

DECISION DOCUMENT for

Salts of Carbonic Acid

Petition No.: no

Tolerance Reassessments?: yes

Chemical Category/Group: mineral acid and salts

The following describes the various ways that salts of carbonic acid are used.

Table 1: Use Pattern (pesticidal - inert ingredient)

Chemical Name	PC Code	40 CFR 180.1001	Inert Use Pattern (Pesticidal)	Current Inert List
ammonium bicarbonate	873401	(c)	surfactant, suspending agent, dispersing agent	4B
magnesium carbonate	873503	(c), (e)	anticaking agent, conditioning agent	4B
potassium carbonate	873504	(d)	buffering agent	4B
sodium bicarbonate	873505	(c)	neutralizer	4A

There is also a tolerance exemption for sodium carbonate 40 CFR 180.2.

The tolerance exemptions for calcium carbonate were reassessed in the IIFG Decision Document "Weathered Materials", dated January 31, 2002. Calcium carbonate is a List 4A

Potassium bicarbonate (40 CFR 180.1177) and sodium bicarbonate (40 CFR 180.1176) are used as active ingredients. (Note that both tolerance exemptions were established post-FQPA.) Potassium bicarbonate is used in six products at 204 use sites, which includes many food crops, as well as ornamentals and turf. It is used against 45 pests including mildew and leaf spot. Sodium bicarbonate is in one product which is a product used only to formulate other pesticides. There are no longer any EPA-registered active ingredient uses for any of the other above-listed carbonate salts.

19977

It is noted that there is information in this document on other carbonate salts for which tolerance exemptions do not currently exist. These data are being used as surrogate data.

Table 2: **Use Pattern (FDA GRAS)**

Chemical	GRAS Citation	GRAS Uses
ammonium bicarbonate	21 CFR 184.1135	dough strengthener, leavening agent, pH control agent, texturizer
ammonium carbonate	21 CFR 184.1137	leavening agent, pH control agent
magnesium carbonate	21 CFR 184.1425	anticaking and free-flow agent, flour treating agent, lubricant and release, nutrient supplement, pH control agent, processing aid, synergist
potassium bicarbonate	21 CFR 184.1613	formulation aid, nutrient supplement, pH control agent, processing aid
potassium carbonate	21 CFR 184.1619	flavoring agent and adjuvant, nutrient supplement, pH control agent, processing aid
sodium bicarbonate	21 CFR 184.1736	(no limitations specified)
sodium carbonate	21 CFR 184.1742	antioxidant, curing and pickling agent, flavoring agent and adjuvant, pH control agent, processing aid

Sodium bicarbonate also is used in food contact surface sanitizing solutions under 21 CFR 178.1010.

20077

Table 3: Use Pattern (non-pesticidal)

Chemical	Uses
ammonium bicarbonate	in baking powder formulations; in cooling baths; fire extinguishers; manufacture of porous plastics, ceramics; manufacture of dyes and pigments; in compost heaps to accelerate decomposition; as fertilizer; for defatting textiles; in cold wave solutions; in chrome leather tanning; to remove gypsum from heat exchangers and other processing equipment.
magnesium carbonate	used to prepare high purity magnesium compounds in the paint and printing inks industries; manufacture of fireproofing, fire-extinguishing, flooring, and polishing compounds; fillers and smoke suppressants in the plastics and rubber industries; USP grade is used as an additive to table salt to keep it free flowing; a bulking compound in powder formulations; an antacid.
potassium carbonate	manufacture of soap, glass, pottery, smalts and many potassium salts; in analytical chemistry; Television glass accounts for a substantial portion of the consumption of potassium carbonate because the potassium salt is more compatible with the lead, barium, and strontium oxides contained in these glasses than is sodium carbonate.
sodium bicarbonate	Leavening agent in baking powder and food ingredients; component of soaps, detergents and pharmaceuticals; agent in leather tanning; textile manufacturing; paper manufacturing; fire extinguishers; in industrial and household chemicals

It should be noted that ammonium bicarbonate can be used as a fertilizer. Plants need various elements (metals and non-metals) for proper growth. Especially for agricultural crops, plants are supplied these elements as part of chemical fertilizers. The most important elements for plant growth are nitrogen, phosphorus, and potassium. Other metals needed in the soil for plant up-take are calcium, magnesium, iron, and trace elements such as zinc. Ammonium bicarbonate can be intentionally added to growing agricultural crops as needed to promote plant growth.

Assessment of the Salts of Carbonic Acid

The ammonium, sodium, potassium, and magnesium salts of carbonic acid are being assessed as a group due to their chemical similarities. However, these salts all contain either the bicarbonate ion (HCO_3^{-1}) or the carbonate ion (CO_3^{-2}), and thus share some common chemistries. A major focus of this assessment is the work previously performed by FDA in assessing the safety of these chemicals as food additives.

1. Physical/Chemical Properties:

The physical and chemical properties of the salts of carbonic acid are described in the May 7, 2002 EFED Assessment. See attached.

2. Information Sources:

The following information was used in performing this assessment: The available information consisted of information retrieved from various websites, such as,

- EPA (www.epa.gov),
- NIOSH, (www.cdc.gov/niosh/ipcsneng/neng1333.html), (www.cdc.gov/niosh/ipcsneng/neng0969.html),
- TOXNET (www.toxnet.nlm.nih.gov.),
- WHO (www.inchem.org/documents/jecfa/jecmono/v17je02.htm)

Various FDA GRAS Assessments were also used.

3. NIOSH (National Institute for Occupational Safety and Health)

The NIOSH International Chemical Safety Card for ammonium hydrogen carbonate indicates that a TLV (Threshold Limit Value) has not been established. The chemical can irritate the skin and the respiratory tract.

The NIOSH International Chemical Safety Card for magnesium carbonate indicates a TLV (Threshold Limit Value) of 10 mg/m^3. The chemical may have effects on the lungs if the magnesite (the naturally occurring form of magnesium carbonate) contains more than 1% crystalline silica.

4. Acid Characteristics

An acid is a substance that when dissolved in water yields H^+ ions. The increase of the concentration of the H^+ ions lowers the pH. Mineral acids contain a non-metal such as phosphorus, nitrogen, sulfur, or chlorine which may or may not be combined with oxygen. When combined with oxygen, these anions can be referred to as oxyanions. Strong acids are those acids that when dissolved completely transfer their H^+ ions to water. Others acids such as carbonic are referred to as weak acids: they exist in solution as a mixture of acid molecules and various ions formed by the dissociation of the acid molecule. The predominant anions for carbonic acid are bicarbonate (HCO_3^{-1}) at pHs below 8 and carbonate (CO_3^{-2}) at pHs above 10.

5. Cations: Sodium, Potassium, and Magnesium

Generally, when any salt of an acid, such as carbonic acid, is dissolved in water, dissociation yields the anions, which are negatively charged, and a positively charged cation. In the human body, these salts tend to dissociate and thus, for the most part, react in the body as the anion and the cation.

Metals such as sodium, magnesium, and potassium are required for proper functioning of human biological systems. For risk assessment purposes an important feature of these metals is

that overall the body does have an effective means of processing them. The primary means of exposure to these cations is ingestion. Four of the most common cations required for functioning of human biology are: sodium, potassium, calcium and magnesium. Chemically, sodium and potassium belong to the same chemical family: calcium and magnesium belong to a different chemical family.

Sodium:

The average human body burden of sodium is approximately 20 grams (g) for a 70 kilogram (kg) adult. The sodium cation is necessary for the nerves and muscles to function properly. It is the principal cation of extracellular fluid, and helps to maintain the body's water balance. These electrolytes, the electrically charged ions in the body fluids, consist to a great extent of sodium and potassium. There is no Recommended Dietary Allowance (RDA) for sodium.

Potassium:

The average human body burden of potassium is approximately 140 g for a 70 kg adult. The potassium cation is important in regulating blood pressure, regulating cellular water content, maintaining proper pH balance, and transmission of nerve impulses. It helps to regulate the electrical activity of the heart and muscles. The potassium RDA is 900 mg/day.

Magnesium:

The average human body burden of magnesium is approximately 20 g for a 70 kg adult. The magnesium cation is also used in building bones. It plays a role in releasing energy from muscles and regulating body temperature. The RDA for magnesium is 310 to 320 mg/day for adult females and 400 to 420 mg/day for adult males with the RDA increasing with increasing age.

6. Ammonium Salt:

Ammonium carbonate salts dissociate to form the positively charged ammonium cation (NH_4^+). Humans cannot convert atmospheric nitrogen to any form that can be used as part of any of the various metabolic cycles. Therefore, reduced nitrogen (NH_4^+) has to enter the body from an outside source. These sources are the nitrogen-containing amino acids in protein which are consumed daily as part of the diet. Although the human body can produce some amino acids, ten amino acids are considered "essential" amino acids, i.e., they must be consumed in the diet.

Generally the body works to maintain a balance of nitrogen intake and nitrogen excretion. The estimated daily ammonia intake through food and drinking water is 18 mg. In contrast, 4000 mg of ammonia per day are produced endogenously in the human intestine.

Ammonia and the ammonium ion are integral components of normal human metabolic processes. Ammonia is released following deamination that occurs when protein is used by the body for energy production. The liver converts ammonia via the urea cycle into urea. According to FDA in the "Evaluation of the Health Aspects of Certain Ammonium Salts as Food Ingredients" (1974), "the normal liver so readily detoxifies ammonium ion from alimentary sources that blood concentrations of ammonium salts do not rise to the levels necessary to evoke toxic response." Approximately 80% of the body's excess nitrogen is eliminated through the kidneys as urea, approximately 25 to 30 grams per day.

24q 77

7. Toxicological Profile Table

The Agency has not reviewed any of the toxicological studies in the following table for any of the salts of carbonic acid. The reviews of these studies were obtained from Toxnet, as well as other government websites.

Table 4: Toxicological Profile

Chemical	Toxicity	Other Information
Ammonium carbonate	Contact with eyes or skin causes irritation, if inhaled will cause difficulty in breathing; Ammonium compounds used as fertilizers are a toxicological hazard when livestock have access to residues or pools of solution on a pasture	CERCLA Reportable Quantity: greater than 5000 lb (2270 kg); Designated as a hazardous substance under section 311(b)(2)(A) of the Federal Water Pollution Control Act and further regulated by the Clean Water Act
Ammonium bicarbonate	Inhalation may cause respiratory irritation; Contact with eyes or skin causes irritation; There appears to be a more rapid excretion of ammonia following ammonium bicarbonate infusions, which result in higher unionized ammonia levels in blood compared with those following ammonium chloride infusions; Mutagenicity: Ames assays strains TA 97 and TA102 with and without rat liver activation: Negative.	CERCLA Reportable Quantity: greater than 5000 lb (2270 kg); Designated as a hazardous substance under section 311(b)(2)(A) of the Federal Water Pollution Control Act and further regulated by the Clean Water Act
Magnesium Carbonate	Repeated doses may cause diarrhea, which may cause fluid and electrolyte imbalance; Can cause hypermagnesemia in those with severely impaired renal function; Can alkalinize the urine; Magnesium salts are poorly absorbed from the intestine; Normal range of magnesium serum concentrations 1.5 to 2.5 mEq/L	1974 Production in US: 5.4 x 10^6 kg (1227 tons), with another 2% of that amount imported that year.

Potassium Carbonate	Oral LD_{50}: Rat 1870 mg/kg; Mouse 2570 mg/kg; Inhalation LC_{50}: Rat > 500 mg/m^3; Irritating to skin , mucous membrane of eyes and upper respiratory tract; Irritant and caustic action similar to that of potassium hydroxide, but less severe; Negative in the Ames assays with two strains of *Salmonella typhimurium* (TA 97 and TA102) with and without activation	Common Name: Potash.
Sodium Bicarbonate	Developmental Toxicity: No effects found up to 580 mg/kg in mice, 340 mg/kg in rats, and 330 mg/kg in rabbits; Negative in the Ames assays with two strains of *Salmonella typhimurium* (TA 97 and TA102) with and without activation; Daily doses up to 25 mEq/kg were administered to patients for 3 weeks, changes in plasma electrolyte concentration were not remarkable, plasma total carbon dioxide increased by only 5 mEq/L with largest dose, considerable weight gain was most prominent effect; No reports of toxicity caused by the ingestion of baking soda; Daily dose limited to 200 mEq in persons under 60 year age and 100 in those older; Adults with normal renal function can tolerate up to 1700 mEq daily with minimal symptoms; Contra indicated for alkalosis (metabolic or respiratory), chloride loss due to vomiting or continuous GI suction, or hypocalcemia; Eliminated principally in the urine, alkalizes it	Common Name: Baking soda. 1984 Production in US: 3.2 x 10^8 kg (72727 tons), with another 5% of that amount imported same year.

269 77

Sodium Carbonate	Oral LD_{50}: rat 2880 to 4090 mg/kg; Inhalation LC_{50}: rat 2300 mg/m^3 (2 hour); Inhalation LC_{50}: mouse 1200 mg/m^3 (2 hour); Skin irritation: mild; Eye irritation : mild-moderate; Aqueous solutions are strongly alkaline; Concentrated solutions tend to produce local necrosis of mucous membranes; Sensitivity reactions may occur from repeated topical use; Ingestion of large quantities may produce corrosion of GI tract, vomiting, diarrhea, circulatory collapse, death; Dusts of vapors of sodium carbonate may cause irritation of mucous membranes with subsequent coughing and shortness of breath; A primary irritant at concentrations below 15% and caustic at concentrations above approximately 15%, depending on contact time, areas of exposure, and other factors; Developmental toxicity test on gestation days 6 to 15 in rats, mice and rabbits at levels of 3.4 to 340 mg/kg: no effects on nidation or survival of the dams or fetuses.	Common name: washing soda

8. Agency Review of Toxicity Data for Potassium Bicarbonate and Sodium Bicarbonate

Sodium bicarbonate has an acute oral LD_{50} greater than 5000 mg/kg in rats, an acute dermal LD_{50} greater than 2000 mg/kg in rabbits, and an acute inhalation LC_{50} greater than 4.74 mg/L in rats. It causes minimal eye irritation and slight dermal irritation in rabbits, and is a dermal non-sensitizer in guinea pigs.

Potassium bicarbonate has an acute oral LD_{50} greater than 2825 mg/kg in rats, an acute dermal LD_{50} greater than 2000 mg/kg in rabbits, and an acute inhalation LC_{50} greater than 4.96 mg/L in rats. It causes slight eye irritation and slight dermal irritation in rabbits, and is a dermal non-sensitizer in guinea pigs.

9. FDA GRAS (Generally Recognized As Safe) Assessments

The FDA Assessment is titled "Evaluation of the Health Aspects of Carbonates and Bicarbonates as Food Ingredients" (1975). "Carbonates and bicarbonates are used in foods as neutralizers and leavening agents. These anions occur in body fluids and tissues as the result of normal metabolic processes and are important in the control of acid-base balance. Except for calcium, most....are fairly soluble in water." The possible average daily intake of added carbonates (i.e., those used as food additives) at that time were:

Table 5: Daily Intake

Chemical Name	0 to 5 Months (mg/kg)	6 to 11 Months (mg/kg)	12 to 23 Months (mg/kg)	2 to 65+ Years (mg/kg)
ammonium bicarbonate	3	12	18	8
ammonium carbonate	8	34	35	12
magnesium carbonate	2	8	12	6
potassium bicarbonate	11	2	<1	---
potassium carbonate	3	15	22	10
sodium bicarbonate	29	171	251	80
sodium carbonate	t	6	6	2

Potassium and Sodium Carbonate and Bicarbonate

In the FDA Assessment acute, short-term, and developmental toxicity studies and mutagenicity studies were evaluated for potassium carbonate and bicarbonate. For sodium

28977

carbonate and bicarbonate acute, short-term, and developmental toxicity studies, and mutagenicity and metabolism studies were evaluated. There was also some human data. No chronic studies were identified.

> "The results of acute toxicity and short-term feeding experiments are not readily extrapolated in determining toxic levels for carbonate salts consumed by humans. Treatment of gastric or peptic ulcers in patients with large amounts of carbonate salts in various forms has been utilized for many years and only rarely have deleterious results of changes of acid-base balance been reported. When the human respiratory and renal functions are normal, the mechanisms for disposing of bicarbonate intake in large amounts through excretion appear to be highly efficient."

> "There is no evidence in the available information on ... potassium carbonate, potassium bicarbonate, sodium carbonate, [or] sodium bicarbonate ... that demonstrates or suggests reasonable grounds to suspect a hazard to the public when used at levels that are now current or that might reasonably be expected in the future."

Ammonium Carbonate and Bicarbonate

The FDA Assessment is titled "Evaluation of the Health Aspects of Certain Ammonium Salts as Food Ingredients" (1974).

> "Ammonia and ammonium ion are integral components of normal metabolic processes and play an essential role in the physiology of man. Although there have been no significant feeding studies specifically designed to ascertain the safety threshold of ammonium compounds as food ingredients, numerous metabolic studies have been reported in the scientific literature. Extrapolation of these finding to the concentrations of ammonium compounds normally present in foods does not suggest that there would be untoward effects at such levels."

Magnesium Carbonate

The FDA Assessment is titled "Evaluation of the Health Aspects of Magnesium Salts as Food Ingredients" (1976). Magnesium is (1) a dietary essential, (2) involved in many metabolic reactions, (3) important in electrolyte balance, and (4) present in fruits, vegetables, grains, milk, meat and fish. No chronic toxicity data were available. The "status of magnesium as a ubiquitous and essential dietary ingredient for the maintenance of homeostatic and bioenergetic mechanisms leads to the opinion that none of the available evidence suggests any probable hazard when any of the GRAS compounds of magnesium is used as a food ingredient." The conclusion was reached that there was no available information on magnesium chloride to demonstrate, or suggest "reasonable grounds to suspect, a hazard to the public when ... used at

levels that are now current and in the manner now practiced, or which might reasonably be expected in the future."

10. FAO/WHO Expert Committee on Food Additives

Ammonium carbonate and ammonium hydrogen carbonate (previously known as ammonium bicarbonate) were evaluated previously in 1966. The evaluation was performed using the available data on ammonium carbonate and ammonium bicarbonate as well as surrogate data on ammonium chloride and various carbonate salts. Acute, short-term, and developmental toxicity studies, mutagenicity studies, and human studies were used.

> "These compounds (ammonium ion and bicarbonate ion) are normal metabolites in man. Although specific toxicological data for ammonium carbonate and ammonium bicarbonate are limited, extrapolation of results from studies with ammonium compounds (primarily ammonium chloride) and with sodium or potassium carbonate provide a basis for evaluation. Clinical studies in man show that administration of high doses of ammonium chloride or of sodium bicarbonate results in changes in the acid-base balance. This is the normal physiological response. The levels of ammonium carbonate and bicarbonate in the diet from food additive use are extremely small compared to the levels required to cause physiological changes and pose no toxicological hazard."

The estimate of acceptable daily intake for man is "not specified." "The statement 'ADI not specified' means that, on the basis of the available data (toxicological, biochemical, and other), the total daily intake of the substance, arising from its use or uses at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of the Committee, represent a hazard to health. For this reason, and for the reasons stated in individual evaluations, the establishment of an acceptable daily intake (ADI) in mg/kg bw is not deemed necessary."

11. Human Health Hazard Characterization:

When dissolved in water, salts of carbonic acids form basic solutions. The toxicity (the irritation and caustic effects) of these chemicals tend to resemble those of the hydroxides, although to a lesser extent. In solution these chemicals could effectively perform as buffering agents, pH adjusters, or neutralizers in pesticide products. This is indicative of the use of small amounts of the chemical that are incorporated in a pesticide product to modify and/or control the pH. After the pH adjustment is performed, the aqueous solution of carbonate salts would be neutralized. If used as an active ingredient the chemical is subject to FIFRA registration requirements and various labeling language. These chemicals must be used and applied according to good manufacturing or good agricultural practices. However, there are no significant adverse effects, to the general public or any population subgroup from consumption

of residues of the ammonium, potassium, magnesium, and sodium salts of carbonic acid resulting from pesticide product uses.

As a group these salts of carbonic acid constitute a group of chemicals with many uses including direct use in the food supply. Various ammonium, magnesium, potassium, and sodium salts of carbonic acid have been reviewed by both FDA and WHO. These chemicals have been used in the food supply for a number of years.

The available toxicity data indicates that the human body metabolizes carbonates, ammonium, magnesium, potassium, and sodium ions through well-understood pathways. In fact, the metals are necessary human nutrients. Given the long history of safe use, the available toxicity data, and an understanding of the human body's ability to metabolize these chemicals, and the evaluations by FDA and WHO, the IIFG believes that ammonium, potassium, sodium and magnesium carbonate salts are of low oral toxicity.

12. Type of Risk Assessment/Risk Characterization:

The toxicity of these chemicals derives from the irritation and caustic effects; therefore, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate.

Given the widespread occurrence of these chemicals in the existing food supply, the amounts that can be applied to food as a result of a use in a pesticide product would not be expected to significantly increase the existing amounts in the food supply. There is no available information on any of the chemicals considered in this document indicative of a human health hazard resulting from the EPA-regulated uses as well as the FDA GRAS uses to the general public or any population subgroup. No additional information is needed to assess their safety.

13. Sensitivity of Infants and Children:

Overall, when considering the oral pathway (ingestion), these chemicals have low toxic potential. At this time, there is no concern for potential sensitivity to infants and children. A safety factor analysis has not been used to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

14. Environmental Fate and Ecotoxicity Assessment/Characterization:

In general, the constituents of the salts of carbonic acid are commonly found in soil and water in the environment suggesting that releasing low levels of these chemicals would not normally be expected to adversely effect wildlife or water resources. Large releases may adversely affect wildlife and water resources either directly or indirectly. Direct effects may result from exceeding toxicity thresholds of specific chemicals. Indirect effects may be manifested through disrupting ecosystems through altering pH or increasing availability of algal

nutrients.

The magnitude of the pH changes, and thus the magnitude of effects, would depend on a number of factors including the amount of material released and the buffering capacity of the exposed soil or water. Normal aquatic pHs range from 5 to 9. EPA's Office of Water recommended water quality criteria for pH are 6.5 to 9 for freshwater and 6.5 to 8.5 for saltwater. At higher or lower pH aquatic life is expected to be adversely impacted. In addition, rapid changes in pH can also be detrimental to aquatic life.

The magnesium, potassium and sodium salts of carbonic acid should dissociate in water resulting in a positively charged (cation) metal in solution. Dissociation is frequently dependent on pH, with lower (more acidic) pHs resulting in higher levels of dissociation and greater solubility. Aquatic toxicity of metals varies with the species of metal and its concentration. Metals do not degrade and thus are permanent in the environment. They are likely to dissipate by being sequestered in soil, sediment, and plants.

15. Cumulative Exposure:

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide chemical's residues and "other substances that have a common mechanism of toxicity." The chemicals considered in this document are structurally related; however, these salts of carbonic acid are low toxicity chemicals. Therefore, the resultant risks separately and/or combined should also be low. EPA does not have, at this time, available data to determine whether these pesticide chemicals have a common mechanism of toxicity with other substances or how to include these pesticide chemicals in a cumulative risk assessment.

16. Determination of Safety:

Based on its review and evaluation of the available information, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to residues of ammonium, sodium, potassium, and magnesium salts. Therefore, the following exemptions from the requirement of a tolerance are reassessed: In 40 CFR 180.2 sodium carbonate. In 40 CFR 180.1001 (c) ammonium bicarbonate, magnesium carbonate, and sodium bicarbonate. In 40 CFR 180.1001 (d) potassium carbonate. In 40 CFR 180.1001 (e) magnesium carbonate.

17. List Reclassifications:

The following List reclassifications are made or confirmed:

Ammonium bicarbonate: List 4B
Ammonium carbonate: List 4B

Magnesium carbonate (less than 1% crystalline silica): List 4A given its similarities to calcium carbonate
Potassium Bicarbonate: List 4A given its similarities to sodium bicarbonate
Potassium Carbonate: List 4B given its similarities to potassium hydroxide
Sodium Bicarbonate: List 4A considering its use as baking soda
Sodium Carbonate: List 4B given its similarities to potassium carbonate

Given the chemical similarities, and that data/information on the following chemicals was used as surrogate data for tolerance reassessment, exemptions from the requirement of a tolerance may be established for ammonium carbonate, potassium bicarbonate, and sodium carbonate.

The following table lists the various chemical names, CAS Reg. No., and CAS Index Names that will be used for listing in 40 CFR.180. Note that both the anhydrous and the hydrated forms are included. The Agency sees no reason to distinguish between these chemicals given that the only difference is the attachment of the water molecules.

Chemical Name	CAS. Reg. No.	Chemical Abstacts Index Name
ammonium bicarbonate	1066-33-7	Carbonic acid, monoammonium salt (8CI, 9CI)
ammonium carbonate	10361-29-2	Carbonic acid, ammonium salt (8CI, 9CI)
ammonium carbonate	506-87-6	Carbonic acid, diammonium salt (8CI, 9CI)
magnesium carbonate	546-93-0	Carbonic acid, magnesium salt (1:1) (8CI, 9CI)
potassium carbonate	584-08-7	Carbonic acid, dipotassium salt (8CI, 9CI)
potassium hydrogen carbonate {KHCO3}	298-14-6	Carbonic acid, monopotassium salt (8CI, 9CI)
potassium carbonate trihydrate {2K2CO3 .3H2O}	18662-52-7	Carbonic acid, dipotassium salt, trihydrate (8CI)
sodium bicarbonate {NaHC03}	144-55-8	Carbonic acid monosodium salt (8CI, 9CI)
sodium carbonate {Na2CO3}	497-19-8	Carbonic acid disodium salt (8CI, 9CI)
sodium carbonate decahydrate {Na2CO3 . 10H2O}	6132-02-1	Carbonic acid disodium salt, decahydrate (8CI, 9CI)
sodium carbonate heptahydrate {Na2CO3 . 7H2O}	56399-31-6	Carbonic acid disodium salt, heptahydrate (9CI)
sodium carbonate monohydrate {Na2CO3 . H2O}	5968-11-6	Carbonic acid disodium salt, monohydrate (8CI, 9CI)

Chemical Name	CAS. Reg. No.	Chemical Abstacts Index Name
sodium sesquicarbonate {Na2CO3 . NaHCO3 . 2H2O}	533-96-0	Carbonic acid, sodium salt (2:3) (8CI, 9CI)

Attachment:

EFED Review of Mineral Acids (Birchfield; May 7, 2002)

INERT INGREDIENT FOCUS GROUP

DECISION DOCUMENT for

Phosphoric Acid and Salts, including the Pyrophosphates and Polyphosphates

Petition No.: no

Tolerance Reassessments?: yes

Chemical Category/Group: mineral acid and salts

The following describes the various ways that phosphoric acid and its salts, including the pyrophosphates and polyphosphates are used.

Table 1: Use Pattern (pesticidal - inert ingredient)

Chemical Name	Inert PC Code	40 CFR 180.1001	Inert Use Pattern (Pesticidal)	Current Inert List
phosphoric acid	876001	(c)	buffer	3
monoammonium phosphate	900088	(c)	Not more than 3.75% by weight in formulation; postharvest fumigation in formulation with aluminum phosphide	4B
diammonium phosphate	900255	(d)	buffer, surfactant	4B
calcium phosphate	876401	(c)	solid diluent, carrier	4B
tricalcium phosphate	876401	(c)	surfactant, suspending agent, dispersing agent, anticaking agent, conditioning agent	4B
potassium phosphate	876400	(c)	buffer	4B
potassium dihydrogen phosphate	900151	(d)	buffering agent	4B
sodium dihydrogen phosphate	776409	(d)	buffering agent	4B
disodium phosphate	876409	(c)	anticaking agent, conditioning agent	4B

trisodium phosphate	876406	(c), (e)	surfactant, emulsifier, wetting agent precipitant, buffer, filler	4B
zinc orthophosphate	876769	(d)	plant nutrient and safener	3
ammonium polyphosphate		(d)	sequestrant, buffer, surfactant	3
tetrapotassium pyrophosphate	876408	(d)	not to exceed 10% of formulation; sequestrant, anticaking agent, conditioning agent	3
sodium acid pyrophosphate	876411	(c)	surfactant, suspending agent, dispersing agent, buffer	4B
sodium hexametaphosphate	900112	(c)	surfactant, emulsifier, wetting agent, suspending agent, dispersing agent, buffer	4B
sodium tripolyphosphate	800010	(c)	buffer, surfactant, suspending agent, dispersing agent, anticaking agent, conditioning agent	4B
tetrasodium pyrophosphate	876405	(c)	anticaking agent, conditioning agent	4B

At this time, only phosphoric acid, potassium dihydrogen phosphate, and trisodium phosphate are used as active ingredients. There are no longer any EPA-registered active ingredient uses for any of the other above-listed phosphate salts.

Table 2: Use Pattern (pesticidal - active ingredient)

Chemical Name	Active PC Code	40 CFR	Number of Products	Active Use Pattern (Pesticidal)
phosphoric acid	076001	none	63	used to kill bacteria, viruses, mold and mildew on dairy and zoo animals; dairy/ milking equipment; drinking water systems, food processing areas and eating establishments; egg washing
potassium dihydrogen phosphate	076413	180.1193 (established post-FQPA)	2	used to kill mildew on food crops, ornamentals and turf
trisodium phosphate	076406	none	2	used to kill bacteria in whirlpool baths and commercial areas

36978

Table 3: Use Pattern (FDA GRAS)

Chemical	GRAS Citation	GRAS Uses
phosphoric acid	21 CFR 182.1073	(no limitations specified)
ammonium phosphate (monobasic)	21 CFR 184.1141a	dough strengthener, pH control agent
ammonium phosphate (dibasic)	21 CFR 184.1141b	dough strengthener, firming agent, leavening agent, pH control agent processing aid
calcium phosphate (includes mono-, di-, and tricalcium)	21 CFR 182.1217	(no limitations specified)
	21 CFR 182.8217	nutrients
calcium phosphate (monobasic)	21 CFR 182.6215	sequestrant
magnesium phosphate	21 CFR 184.1434	nutrient supplement, pH control agent
dipotassium phosphate	21 CFR 182.6285	sequestrant
sodium acid phosphate	21 CFR 182.6085	sequestrant
sodium phosphate (includes mono-, di-, and trisodium)	21 CFR 182.1778	(no limitations specified)
	21 CFR 182.6778	sequestrant
	21 CFR 182.8778	nutrients
disodium phosphate	21 CFR 182.6290	sequestrant
calcium pyrophosphate	21 CFR 182.8223	nutrients
calcium hexametaphosphate	21 CFR 182.6203	sequestrant
sodium acid pyrophosphate	21 CFR 182.1087	(no limitations specified)
sodium tripolyphosphate	21 CFR 182.1810	(no limitations specified)
	21 CFR 182.6810	sequestrant

37 of 78

sodium hexametaphosphate	21 CFR 182.6760	sequestrant
sodium metaphosphate	21 CFR 182.6769	sequestrant
sodium pyrophosphate	21 CFR 182.6787	sequestrant
tetrasodium pyrophosphate	21 CFR 182.6789	sequestrant

Phosphoric acid, trisodium phosphate, and sodium dihydrogen phosphate also have uses in food contact surface sanitizing solutions under 21 CFR 178.1010.

Table 4: Use Pattern (non-pesticidal)

Chemical	Uses
phosphoric acid	over 90% of the phosphoric acid produced in the United States and worldwide is used for agricultural applications as both fertilizers and animal feed supplements; used in the manufacture of superphosphates for **fertilizers**, other phosphate salts, polyphosphates, detergents; as an acid catalyst in making ethylene, purifying hydrogen peroxide; acidulant and flavor, synergistic antioxidant and sequestrant in food; pharmaceutic aid (solvent); dental cements; process engraving; rustproofing of metals before painting; coagulating rubber latex; analytical reagent.
monoammonium phosphate	as baking powder with sodium bicarbonate; in fermentations (yeast cultures, etc.); fireproofing of paper, wood, fiberboard, etc.; used to protect pesticides in spray mixtures prepared with alkaline waters
diammonium phosphate	fireproofing textiles, paper, wood, and vegetable fibers; impregnating lamp wicks; preventing afterglow in matches; flux for soldering tin, copper, brass, and zinc; purifying sugar; in yeast cultures; in dentifrices; in corrosion inhibitors; in fertilizers.
calcium phosphate	in **fertilizers**; acidulant in baking powder and wheat flours; in enameling; mineral supplement for foods & feeds
tricalcium phosphate	manufacture of **fertilizers**, H3PO4 and phosphorous compounds; manufacture of milk-glass, polishing and dental powders, porcelains, pottery; enameling; clarifying sugar syrups; animal feeds; anticaking agent; in the textile industry; stabilizer for plastics; in meat tenderizers; in food as buffer
monopotassium phosphate	widespread use is as a mineral nutrient for fermentation broths; special liquid **fertilizers**, buffering systems, paper processing; piezoelectric properties has led to its use in sonar systems and other electronic applications.
potassium dihydrogen phosphate	buffers for determination of pH; pharmaceutical aid (buffering agent); baking powder; nutrient solutions; yeast foods; buffer and sequestrant in foods; widespread use as a mineral nutrient for fermentation broths; special liquid **fertilizers**, buffering systems; paper processing.

3390 78

Table 4: Use Pattern (non-pesticidal)

Chemical	Uses
sodium dihydrogen phosphate	in baking powders; in boiler water treatment; as dry acidulant and sequestrant for foods; buffering agent (electroplating baths); acidulant (processed meats, egg products, powdered drinks); builder (industrial cleaning formulations); metal phosphatising reagent; mineral supplement; softening/conditioning agent (boiler water treatment); textile dyeing/printing auxiliary
disodium phosphate	emulsifier (processed cheese, quick-cook cereals, pharmaceuticals); metal phosphatising/electroplating reagent); pottery glazes/porcelain/enamels; scale inhibitor (boiling water treatment); textile/leather auxiliary; detergents
trisodium phosphate	removing insecticide residues from fruit; inhibiting mold; photographic developers; clarifying sugar; removing boiler scale, softening water; manufacture of paper; laundering; tanning leather; in detergent mixture; dairy substitutes (milk-based pudding, sour cream, cheese).
ammonium polyphosphate	intermediate in the production of high quality liquid fertilizers; stabilizer in skimmed sweetened condensed milk and dry milk; condensed acids of 82-84% P2O5 content are employed as catalysis in the petroleum and chemical industries for alkylation, dehydrogeneration, polymerization, and isomerization reactions, including ethylbenzene, gasoline, and plasticizer alcohols.
Sodium hexametaphosphate	aka Calgon; softening water without precipitate formation in dyeing, laundering, textile processing, and washing operations; corrosion inhibitor in de-icing salt preparations; frozen desserts; pretanning hides in the manufacture of leather; dispersing clays and pigments; threshold treatment for scale; and corrosion prevention.
sodium tripolyphosphate	one of the most widely used and most effective builder in heavy-duty fabric washing compositions; because of its high sequestration power, extensive application in automatic dish-washing detergents; forms stable hydrates and thus aids in the manufacture of crisp spray-dried laundry powders; texturizer in food; phosphorus source for cattle.
sodium acid pyrophosphate	chiefly in baking powders; food acidulant; electroplating; metal cleaning and phosphatizing; drilling muds buffer; sesquestrent peptizing agent in cheese and meat products; frozen desserts
tetrasodium pyrophosphate	industrial and institutional detergent builder; water treatment; household laundry detergents; processed cheeses; other food applications; textile and clay processing; elastomers; paper processing

It should be noted that several of the phosphates have uses as fertilizers, or as chemicals used in the preparation of fertilizers. Plants need various elements (metals and non-metals) for proper growth. Especially for agricultural crops, plants are supplied these elements as part of chemical fertilizers. The most important elements for plant growth are nitrogen, phosphorus, and potassium. Other metals needed in the soil for plant up-take are calcium, magnesium, iron, and trace elements such as zinc. Fertilizers containing phosphates are intentionally added to growing agricultural crops as needed to promote plant growth.

Assessment of Phosphoric Acid and its Salts

Phosphoric acid and its ammonium, sodium, potassium, calcium, magnesium, and zinc salts are being assessed as a group due to their chemical similarities. Due to its acidic nature the toxicity of phosphoric acid will be different from those of the more neutral phosphate salts. However, these phosphate salts all contain the phosphate ion (as $H_2PO_4^{-1}$, HPO_4^{-2}, or PO_4^{-3}), and thus share some common chemistries. A major focus of this assessment is the work previously performed by FDA in assessing the safety of these chemicals as food additives.

1. Physical/Chemical Properties:

The physical and chemical properties of phosphoric acid and its various salts are described in the May 7, 2002 EFED Assessment. See attached.

2. Information Sources:

The following information was used in performing this assessment: The available information consisted of information retrieved from various websites, such as,

- EPA (www.epa.gov),
- NIOSH, (www.cdc.gov/niosh/ipcsneng/neng1008.html), (www.cdc.gov/niosh/ipcsneng/neng1178.html), (www.cdc.gov/niosh/ipcsneng/neng0983.html), (www.cdc.gov/niosh/ipcsneng/neng0217.html), (www.cdc.gov/niosh/ipcsneng/neng1140.html), (www.cdc.gov/niosh/pdfs/0506.pdf)
- TOXNET (www.toxnet.nlm.nih.gov.)
- WHO (www.inchem.org/documents/jecfa/jecmono/v17je22.htm), (www.inchem.org/documents/jecfa/jecmono/v48je11.htm) (www.inchem.org/documents/jecfa/jecmono/v46je58.htm) and (www.inchem.org/documents/jecfa/jecmono/40abcj39.htm)

Various FDA GRAS Assessments were used, as well as, the FAO/WHO Assessments for phosphoric acid, and various phosphate salts and polyphosphates.

3. NIOSH (National Institute for Occupational Safety and Health)

The NIOSH IDHL (immediately dangerous to life or health) for phosphoric acid is 1000 mg/m^3. The International Chemical Safety Card for phosphoric acid indicates that it is hydroscopic colorless crystals. The TLV (Threshold Limit Value) is 1 mg/m^3. Phosphoric acid is a medium strong acid that reacts violently with bases. Phosphoric acid mist is an irritant to the eyes, upper respiratory tract and skin. A 75% solution will cause severe skin burns.

40 of 78

The NIOSH International Chemical Safety Card for tetrasodium pyrophosphate indicates that the TLV is 5 mg/m^3. No TLVs have been established for trisodium phosphate, tetrapotassium pyrophosphate, and ammonium phosphate dibasic. However, all of the Safety Cards indicate that the chemicals are corrosive or irritating.

4. Acid Characteristics

An acid is a substance that when dissolved in water yields H^+ ions. The increase of the concentration of the H^+ ions lowers the pH. Mineral acids contain a non-metal such as phosphorus, nitrogen, sulfur, or chlorine which may or may not be combined with oxygen. When combined with oxygen, these anions can be referred to as oxyanions. Strong-acids are those acids that when dissolved completely transfer their H^+ ions to water. Phosphoric acid is a medium strong acid.

Acids such as phosphoric exist in solution as a mixture of acid molecules and ions. Phosphoric acid has three hydrogens but only one of them is readily transferred to water, that is, exhibiting the property of a strong acid. The transfer of the other two remaining hydrogens occurs at pHs above 7.

5. Cations: Sodium, Potassium, Calcium, Magnesium, and Zinc

Generally, when any salt of an acid, such as phosphoric acid is dissolved in water, dissociation yields the anions, which are negatively charged, and a positively charged cation. In the human body, these salts tend to dissociate and thus, for the most part, react in the body as the anion and the cation.

Metals such as calcium, sodium, magnesium, potassium, and zinc are also required for proper functioning of human biological systems. For risk assessment purposes an important feature of these metals is that overall the body does have an effective means of processing them. The primary means of exposure to these cations is ingestion. Four of the most common cations required for functioning of human biology are: sodium, potassium, calcium and magnesium. Chemically, sodium and potassium belong to the same chemical family: calcium and magnesium belong to a different chemical family.

Sodium:

The human body burden of sodium is approximately 20 grams (g) for a 70 kilogram (kg) adult. The sodium cation is necessary for the nerves and muscles to function properly. It is the principal cation of extracellular fluid, and helps to maintain the body's water balance. These electrolytes, the electrically charged ions in the body fluids, consist to a great extent of sodium and potassium. There is no Recommended Dietary Allowance (RDA) for sodium.

Potassium:

The human body burden of potassium is approximately 140 g for a 70 kg adult. The potassium cation is important in regulating blood pressure, regulating cellular water content, maintaining proper pH balance, and transmission of nerve impulses. It helps to regulate the electrical activity of the heart and muscles. The potassium RDA is 900 mg/day.

Calcium:

The human body burden of calcium is approximately 1 kg for a 70 kg adult; or 1/70th of our weight is calcium. The calcium cation is necessary for bone and teeth formation. It is also important to the proper functioning of nerves, enzymes, and muscles, and plays a role in blood clotting and the maintenance of cell membranes. The RDAs for calcium are 1000 mg/day for adults aged 19 to 50 years and 1200 mg/day for individuals older than 50 years.

Magnesium:

The human body burden of magnesium is approximately 20 g for a 70 kg adult. The magnesium cation is also used in building bones. It plays a role in releasing energy from muscles and regulating body temperature. The RDA for magnesium is 310 to 320 mg/day for adult females and 400 to 420 mg/day for adult males with the RDA increasing with increasing age.

Zinc:

Another common metal cation that is necessary for human metabolism, but in smaller amounts often referred to as trace, is zinc. The human body burden of zinc is approximately 100 milligram (mg) for a 70 kg adult. Zinc is a component of many enzymes and therefore has substantial involvement in many metabolic processes. It also assists in wound healing, blood formation, and general growth and maintenance of the body's tissues. The RDAs for zinc are 15 mg/day [0.21 mg/kg/day for an adult (70 kg) male] and 12 mg/day [0.2 mg/kg/day for an adult (60 kg) female]. According to FDA, the average daily intake of zinc from food (including water) was 0.23 mg/kg/day in the early 1980s. Consuming too much zinc (i.e. , 10 to 15 times the RDA) can cause health concerns such as anemia, pancreatic and kidney effects, and certain developmental effects. Consuming too little zinc can cause loss of appetite , decreased sense of taste and smell, decreased immune function, slow wound healing, skin sores, and developmental effects.

6. Ammonium Salt:

Ammonium phosphates dissociate to the negatively charged anion and the positively charged ammonium cation (NH_4^+). Humans cannot convert atmospheric nitrogen to any form that can be used as part of any of the various metabolic cycles. Therefore, reduced nitrogen

(NH_4^+) has to enter the body from an outside source. These sources are the nitrogen-containing amino acids in protein which are consumed daily as part of the diet. Although the human body can produce some amino acids, ten amino acids are considered "essential" amino acids, i.e., they must be consumed in the diet.

Generally the body works to maintain a balance of nitrogen intake and nitrogen excretion. The estimated daily ammonia intake through food and drinking water is 18 mg. In contrast, 4000 mg of ammonia per day are produced endogenously in the human intestine.

Ammonia and the ammonium ion are integral components of normal human metabolic processes. Ammonia is released following deamination that occurs when protein is used by the body for energy production. The liver converts ammonia via the urea cycle into urea. According to FDA in the "Evaluation of the Health Aspects of Certain Ammonium Salts as Food Ingredients" (1974), "the normal liver so readily detoxifies ammonium ion from alimentary sources that blood concentrations of ammonium salts do not rise to the levels necessary to evoke toxic response." Approximately 80% of the body's excess nitrogen is eliminated through the kidneys as urea, approximately 25 to 30 grams per day.

7. Toxicological Profile Table

With the exception of the information in IRIS (Integrated Risk Information System), the Agency has not reviewed any of the toxicological studies in the following table for hydrochloric acid or any of its salts. The reviews of these studies were obtained from Toxnet, as well as other government websites.

Table 5: Toxicological Profile

Chemical	Toxicity	Other Information
Phosphoric acid	IRIS: Inhalation RfC: 1 x 10^{-2} mg/m^3 due to bronchiolar fibrosis in a 13 week rat inhalation study There is no Oral RfD and a carcinogenicity assessment has not been completed. Not irritating to the eyes or respiratory tract, unless introduced into the atmosphere as a spray or mist, phosphoric acid has low vapor pressure at room temperature; Topically may irritate and injure the eyes, owing to its acidity, but systemically has no poisonous action on the eye. Tested on human eyes, 0.16 M phosphoric acid buffered to pH 2.5 caused moderate brief stinging sensation, but no injury when applied as a single drop. A drop of the same solution adjusted to pH 3.4 caused no discomfort.	CERCLA Reportable Quantities: 5000 lb (2270 kg); US production (1993): 23.04 billion lb (11,520,000 tons).
Monoammonium phosphate	Acute eye contact with concentrated alkali causes conjunctival edema and corneal destruction. Since alkalies penetrate skin slowly, extent of damage depends on duration of contact. Chronic poisoning may occur from skin contact. Chronic dermatitis may follow repeated contact.	

Diammonium phosphate	Dust irritating to eyes, and throat. Solid irritating to skin and eyes; A 0.1 M solution of ammonium phosphate (pH 7 to 7.5), with sodium chloride and/or sucrose added to make a 0.46 osmolar solution (1.5 x the isotonic concentration) was dripped continuously onto the eyes of rabbits, and caused edema of the epithelium of the cornea within 3 to 3.5 hours.	US production (1975): 5.17×10^9 kg (568,000 tons), with another 40% of that amount imported that year.
Calcium hydrogen phosphate	Normal total serum calcium levels are 4.5 to 5.2 mEq/L. Symptoms may appear when plasma calcium reaches 6.6 mEq/L;	
Calcium bis(dihydrogen phosphate)	In animal feeding studies, levels of 0.5% phosphate in diet could be tolerated without adverse physiological effects, and higher levels could be tolerated if proper balance of ions (calcium, magnesium and potassium) is maintained.	US production (1975): 1.3×10^8 kg (143,000 tons).
Tricalcium phosphate	Mutagenicity: Ames assay with two strains(TA97 and TA102) of *Salmonella typhimurium* with and without activation; Negative.	US production (1976): 2.86×10^8 kg (315,000 tons).
Monopotassium phosphate	Acute oral LDLo (lowest published lethal does) rat: 4640 mg/kg Acute LD_{50} dermal rabbit: >4640 mg/kg Animal-feeding studies indicate that levels of 0.5% phosphate in the diet could be tolerated without adverse physiological effects. Higher levels could be tolerated, if proper balance of ions (calcium, magnesium, and potassium) is maintained; Potassium phosphate causes sever ulceration in the GI tract at a level equivalent to 1000 mg potassium ion when given to monkeys in the form of a pill;	US production (1976:1.82 - 2.72 x 10^8 kg (2002 - 2992 tons)

Dipotassium phosphate	After oral administration of 800 mg/kg body wt for 14 or 38 weeks, dogs vomited, were cachectic, and had elevated creatinine and blood urea nitrogen. Renal damage was most marked at 38 week, with disseminated atrophy (usually of proximal tubules), focal scar tissue, and nephrocalcinosis; Animal-feeding studies indicate that levels of 0.5% phosphate in the diet could be tolerated without adverse physiological effects. Higher levels could be tolerated, if proper balance of ions (calcium, magnesium, and potassium) is maintained; Potassium phosphate causes sever ulceration in the GI tract at a level equivalent to 1000 mg potassium ion when given to monkeys in the form of a pill; Mutagenicity: Ames assay with two strains (TA97 and TA102) of *Salmonello typhimurium* with and without activation: Negative.	US production (1975): 4.54 - 6.36 x 10^8 kg (568,000 tons)
Tripotassium phosphate	Acute Oral Lowest published lethal dose: Rat: 4640 mg/kg; Acute Dermal LD_{50}: Rabbit: greater than 4640 mg/kg; Irritation: Eye: Rabbit: Moderate; Mutagenicity: Ames assay with two strains (TA97 and TA102) of *Salmonella typhimurium* with and without activation: Negative.	
Disodium phosphate	Acute Oral LD_{50}: Rat: 12,930 to 17,000 mg/kg; Toxicity of parenteral dibasic and monobasic sodium phosphate is due to their sequestration of calcium. Systemic reactions are unlikely when these salts (dibasic and monobasic sodium phosphate) are given by mouth; Anhydrous form may cause mild irritation to skin, mucous membranes, internally causes purging; Dust is irritating to eyes, nose and throat. If inhaled will cause coughing or difficult breathing. Solid is irritating to skin and eyes; A 0.1 M solution of *sodium phosphate* (pH 7 to 7.5), with sodium chloride and/or sucrose added to make a 0.46 osmolar solution, caused no disturbance in the cornea of rabbit eyes; Mutagenicity: Salt tested in Ames assay with four strains (TA100, TA1535, TA1537, and TA98) of *Salmonella typhimurium* with and without activation: Negative; Distilled water solutions tested in Ames assay with six strains (TA100, TA1535, TA1537, TA98, TA97 and TA102) of *Salmonella typhimurium* with and without activation: Negative.	CERCLA Reportable Quantities: 5000 lb (2270 kg); Clean Water Act Requirements: Designated as a hazardous substance under section 311(b)(2)(A) of the Federal Water Pollution Control Act and further regulated by the Clean Water Act Amendments of 1977 and 1978; US production (1984): 2.87 x 10^7 kg (31,570 tons).

Sodium dihydrogen phosphate	Acute Oral LD50: Rat: 8290 mg/kg; Doses of 250 g/kg by mouth produced diarrhea in rats, guinea pigs, and rabbits; Toxicity of parenteral dibasic and monobasic sodium phosphate is due to their sequestration of calcium. Systemic reactions are unlikely when these salts (dibasic and monobasic sodium phosphate) are given by mouth; Phosphates (dibasic & monobasic sodium phosphate) are slowly and incompletely absorbed.	US production (1975): 3.73×10^7 kg (41,030 tons).
Trisodium phosphate	Acute Oral LD50: Rat: 7400 mg/kg; Acute Dermal LD50: Rabbit: > 300 mg/kg; Aqueous solutions are highly alkaline, and may produce caustic burn; Splash of aqueous solution of trisodium phosphate in human eyes in one case, caused slight transient injury, and in two other cases, caused moderate permanent corneal opacification and vascularization (similar to that caused by sodium hydroxide).	CERCLA Reportable Quantities: 5000 lb (2270 kg); Clean Water Act Requirements: Designated as a hazardous substance under section 311(b)(2)(A) of the Federal Water Pollution Control Act and further regulated by the Clean Water Act Amendments of 1977 and 1978. US production in US (1975): 5.1×10^7 kg (56,100 tons).
Tetrapotassium pyrophosphate	Oral: Lowest Published Lethal Dose (LDLo): Rat: 4640 mg/kg Dermal LD50: Rabbit: > 4640 mg/kg	
Sodium acid pyrophosphate	Oral LD_{50}: Mouse: 2650 mg/kg; An irritant to skin, eyes, and mucous membranes.	1972 and 1975 Production in US: 2.48×10^7 kg (27,280 tons) and 2.14×10^7 kg (23540 tons), respectively

Sodium tripolyphosphate	Oral LD50: Rat: 3120 mg/kg; Stricture of esophagus can occur up to years later, causing difficulty swallowing. Irritating because of its alkalinity and hypertoxicity. If ingested in large amounts nausea, vomiting and diarrhea are possible. Less corrosive effect on mucous membranes than sodium or potassium hydroxide; Tripolyphosphates are thought to be hydrolyzed to (ortho)phosphates before absorption in the gastrointestinal tract; Mutagenicity: Ames assays with five strains (TA98, TA100, TA1535, TA1537, and TA1538) of *Salmonella typhimurium* with and without activation: Negative. A strain of *Escherichia coli* (WP2 UVRA) with and without activation: Negative	CERCLA Reportable Quantity: greater than 5000 lb (2270 kg) ; 1984 Production in US: 6.12 x 10^8 kg (673,200 tons), with another 1% of that amount imported that year;
Sodium hexametaphosphate	Oral LD_{50}:: Rat: 6200 mg/kg; Oral LD_{50}: mouse: 4320 mg/kg; Irritating because of its alkalinity and hypertoxicity. If ingested in large amounts nausea, vomiting and diarrhea are possible. The corrosive effect is strong irritation, erythema, blistering; Less corrosive effect on mucous membranes than sodium or potassium hydroxide; 10-40% of the phosphorus in sodium hexametaphosphate is absorbed in intestinal tract, with the balance of phosphorus eliminated in the feces; Feeding study: rats: severe kidney damage at 3 and 5%, but no observable physiological damage at 1.8%; Dog study: began to lose weight when the daily dose reached 2.5 g/kg/day Developmental studies: oral feeding for 10 days: pregnant rats at up to 240 mg/kg and pregnant mice at up to 370 mg/kg: no discernible effects on nidation (nest-building) or on maternal of fetal survival, and no significant effects on soft and skeletal tissues, compared with controls; Mutagenicity: Ames assay with *Salmonella typhimurium* with and without activation: Negative. *Salmonella cerevisiae* with and without activation: Negative.	CERCLA Reportable Quantity: greater than 5000 lb (2270 kg); 1976 Production in US: 6.36 x 10^4 kg (70 tons), minimum consumption in foods.

Tetrasodium pyrophosphate	Medical reports of acute exposures show mild to moderate dermal and ocular responses; Acute study in rabbit eye shows that direct contact causes severe irritation and corneal injury, and may be irritating to skin; 6-Month feeding study: Rat: Maximum dose tolerated was greater than 1.8%, but less than 3%; excess phosphate damage to the kidneys; 1-Year dietary feeding study: Rat: No adverse effect level was 0.1% (approximately 50 mg/kg/day) 16 week rat feeding study - maximum level tolerated was less than 1%	1975 Production in US: 3.1×10^7 kg (34,100 tons)

8. OPP Mineral Acid RED (Reregistration Eligibility Decision Document)

The following information on the acute toxicity of phosphoric acid was in the 1993 RED: The oral LD_{50} is 1530 mg/kg, toxicity category III. The dermal LD_{50} is 2740 mg/kg, toxicity category III. Phosphoric acid is toxicity category I for eye and dermal irritation. No other toxicological data were required based on the use patterns at the time of the issuance of the RED and the corrosiveness shown in the acute studies for dermal and eye irritation.

9. Agency Review of Toxicity Data for Potassium Dihydrogen Phosphate

Sodium dihydrogen phosphate has an acute oral LD_{50} greater than 5000 mg/kg in male rats, an acute oral LD_{50} greater than 500 mg/kg in female rats, an acute dermal LD_{50} greater than 2000 mg/kg in rabbits, and an acute inhalation LC_{50} greater than 4.74 mg/L in rats. It is causes mild eye irritation and is a non-irritant for skin irritation.

10. FDA GRAS (Generally Recognized As Safe) Assessments

Ammonium Phosphate, Monobasic and Dibasic

In the FDA Assessment titled "Evaluation of the Health Aspects of Certain Ammonium Salts as Food Ingredients" (1974), the following general conclusion on ammonium compounds was reached:

> "Ammonia and ammonium ion are integral components of normal metabolic processes and play an essential role in the physiology of man. Although there have been no significant feeding studies specifically designed to ascertain the safety threshold of ammonium compounds as food ingredients, numerous metabolic studies have been reported in the scientific literature. Extrapolation of these findings to the concentrations of ammonium compounds normally present in foods does not suggest that there would be untoward effects at such levels."

Magnesium Phosphate, Dibasic and Tribasic

The FDA Assessment is titled "Evaluation of the Health Aspects of Magnesium Salts as Food Ingredients" (1976). Magnesium is (1) a dietary essential, (2) involved in many metabolic reactions, (3) important in electrolyte balance, and (4) present in fruits, vegetables, grains, milk, meat and fish. There are no chronic toxicity data. The "status of magnesium as a ubiquitous and essential dietary ingredient for the maintenance of homeostatic and bioenergetic mechanisms leads to the opinion that none of the available evidence suggests any probable hazard when any of the GRAS compounds of magnesium is used as a food ingredient." It was concluded that there was no available information on magnesium phosphate that "demonstrates, or suggests

50% 77

reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current and in the manner now practiced, or which might reasonably be expected in the future."

Phosphoric Acid, and Various Ammonium, Calcium, Potassium and Sodium Phosphate Salts

The FDA Assessment is titled "Evaluation of the Health Aspects of Phosphates as Food Ingredients." (1975). For this evaluation FDA reviewed various oral acute, short-term, chronic, developmental, and reproductive toxicity; mutagenicity; and human studies on ammonium, calcium, potassium and sodium phosphate salts. The possible average daily intake of added phosphates (i.e., those used as food additives) at that time were:

Table 6: Daily Intake

Chemical Name	0 to 5 Months (mg/kg)	6 to 11 Months (mg/kg)	12 to 23 Months (mg/kg)	2 to 65+ Years (mg/kg)
phosphoric acid	1	5	7	3
ammonium phosphate dibasic	1	3	4	2
ammonium phosphate monobasic	<1	<1	<1	<1
calcium phosphate, dibasic	807	157	81	18
calcium phosphate, monobasic	33	69	72	22
calcium phosphate, tribasic	170	142	84	13
potassium phosphate, dibasic	3	15	17	7
potassium phosphate, monobasic	<1	6	5	1
potassium tripolyphosphate	<1	<1	<1	<1
sodium acid pyrophosphate	4	28	39	16
sodium metaphosphate	17	31	29	10
sodium phosphate, dibasic	24	121	105	24

51077

sodium phosphate, monobasic	7	36	53	22
sodium phosphate, tribasic	3	25	33	12
sodium pyrophosphate	9	52	70	32
sodium tripolyphosphate	2	13	14	6

"Phosphates are components of all living organisms and provide phosphorus, an essential nutrient." Phosphate is absorbed from the small intestine. Approximately "30 percent of the ingested phosphate is excreted in the feces and 70 percent in the urine." The polyphosphates must undergo hydrolysis to phosphate for absorption to occur.

The FDA Select Committee considered in great detail the interrelationships of calcium, magnesium, and phosphorous. In its opinion it was recognized that there are

> "many variables to be considered regarding the safety to the public of the current uses of phosphates in foods. These include: (a) the variety and different characteristics of phosphates and their scope of use; (b) the close metabolic interrelationships between vitamin D, calcium, and phosphorus; and (c) the possible variations between different segments of the population in the level of phosphate consumed both in foods and in beverages. .....[I]t is the opinion of the Select Committee that the Ca:P ratio of the diet is important, especially if it varies substantially from 1:1 owing to the relatively high intake of phosphorus. Most of the evidence shows that in general a desirable Ca:P ratio is between 2:1 and 1:1. Thus if the calcium intake is 800 mg per person per day the total phosphorus intake should not greatly exceed that amount. The fragmentary data available suggest that the typical Ca:P ratio in this country is lower than 1:1. Some estimates suggest it may be substantially lower. In laboratory animals and presumably in man, nutritional secondary hyperparathyroidism and bone resorption may be inducted when the diet furnishes an other otherwise adequate amount of calcium but excessive levels of phosphorus."

> None of the GRAS phosphates is intrinsically harmful and their use in foods does not present a hazard when the total amount of phosphorus ingested and the intakes of calcium, magnesium, vitamin D, and other nutrients are satisfactory. The current use of calcium phosphates in food processing is without harmful effects on the health of consumers and, in some instances, may be advantageous. The phosphorus supplied by GRAS phosphates, other than calcium phosphates, added

to foods is low in relation to the total amount of phosphorus naturally present in the diet. However, the possibility that unreasonable increases in the usage of these phosphates in common foods would significantly lower the Ca:P ratio and increase the total phosphorus intake for some segments of the population, must be considered in assessing the probability of a health hazard existing because of the ingestion of excessive levels of phosphorus. The Select Committee has no evidence that the use of any of these no-calcium phosphates as food ingredients at current levels is creating such a problem. however, if distortion of the Ca:P ration should become of concern, this question should be accorded separate study."

The select committee considered the above information and then concluded that for phosphoric acid and the salts considered that there "is no evidence in the available information ... that demonstrates or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or that might reasonably be expected in future."

11. FAO/WHO Expert Committee on Food Additives

WHO has performed several assessments on phosphoric acid and on 29 of the various calcium, magnesium, potassium and sodium salts. The latest assessment is undated, but from the references was performed in the early to mid 1980s.

"Metabolically, the phosphate salts provide a source of the various cations and the phosphate ion. Of greatest concern is the toxicity arising from calcium, magnesium and phosphate imbalance in the diet. Phosphate salts were not mutagenic in a number of test systems. Teratogenic effects have not been observed in mammalian test systems.

Numerous animal studies have shown that excessive dietary phosphorus causes an increase of plasma phosphorus and a decrease in serum calcium. The resulting hypocalcaemia stimulates secretion of PTH which in turn increases the rate of bone resorption and decreases calcium excretion. These homeostatic adjustments to high dietary phosphorus may result in bone loss and calcification of soft tissues in animals.

The dose levels of phosphate producing nephrocalcinosis were not consistent among the various rat feeding studies. However, the rat is exquisitely susceptible to calcification and hydronephrosis upon exposure to acids forming calcium chelates or complexes. The lowest dose levels that produce nephrocalcinosis overlap the higher dose levels failing to do so. However, this may be related to other dietary imbalances, such as the level of magnesium in the diet. There is still uncertainty on the optimal Ca:P ratio and whether this ratio is of any dietary significance in man.

The lowest level of phosphate that produced nephrocalcinosis in the rat (1% P in the diet) is used as the basis for the evaluation and, by extrapolation based on the daily food intake of 2800 calories, this gives a dose level of 6600 mg P per day as the best estimate of the lowest level that might conceivably cause nephrocalcinosis in man. The usual calculation for provision of a margin of safety is probably not suitable for food additives that are also nutrients. Ingested phosphates from natural sources should be considered together with that from food additives sources. Since phosphorus (as phosphates) is an essential nutrient and an unavoidable constituent of food, it is not feasible or appropriate to give a range of values from zero to a maximum."

It was determined that the **estimate of maximum tolerable daily intake** for man would be 70 mg/kg bw.

"This figure represents the maximum tolerable daily intake (MTDI) of phosphates. It is not an ADI. The MTDI is expressed as phosphorus and it applies to the sum of phosphates naturally present in food and the additives listed below. It also applies to diets that are nutritionally adequate in respect of calcium. However, if the calcium intake were high, the intake of phosphate could be proportionately higher, and the reverse relationship would also apply."

12. Human Health Hazard Characterization:

Phosphoric acid in its concentrated form is corrosive and irritating. Due to this property toxicity testing can only be performed on dilute concentrations or on neutralized forms of the acid such as a salt. The consequences of acute exposure to phosphoric acid are well-understood.

Exposure to phosphoric acid in pesticide products as an inert ingredient would be in the role of a pH adjuster. This is indicative of the use of small amounts of phosphoric acid that are incorporated in a pesticide product to modify and/or control the pH. After the pH adjustment is performed, the phosphoric acid would be neutralized. As an active ingredient phosphoric acid is subject to FIFRA registration requirements and various labeling language as specified in the 1993 RED. Phosphoric acid must be used and applied according to good manufacturing or good agricultural practices. However, there are no significant adverse effects, to the general public or any population subgroup from consumption of residues of phosphoric acid resulting from pesticide product uses.

As a group these salts of phosphoric acid constitute a group of chemicals with many uses including direct use in the food supply. The human body metabolizes phosphate, ammonium, calcium, magnesium, potassium, sodium and zinc through well-understood pathways. In fact, all are necessary human nutrients. There are no available data to indicate any significant adverse effects to the general public or any population subgroup from consumption of residues of the ammonium, calcium, magnesium, potassium, sodium and zinc salts of phosphoric acid resulting

from pesticide product uses.

Given the long history of safe use, the available toxicity data, an understanding of the human body's ability to metabolize these chemicals, and the evaluations by FDA and WHO, the IIFG believes that ammonium, sodium, potassium, magnesium, calcium and zinc phosphate salts are of low oral toxicity.

13. Type of Risk Assessment/Risk Characterization:

The toxicity of these chemicals derives from the irritation and caustic effects; therefore, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate.

Given the widespread occurrence of phosphoric acid and its salts in the existing food supply, the amounts that can be applied to food as a result of a use in a pesticide product would not be expected to significantly increase the existing amounts in the food supply. There is no available information on any of the salts of phosphoric acid considered in this document indicative of a human health hazard resulting from the EPA-regulated uses as well as the FDA GRAS uses to the general public or any population subgroup. No additional information is needed to assess their safety.

14. Sensitivity of Infants and Children:

Due to its acidic nature, its corrosive potential, there is high acute toxicity for phosphoric acid. Phosphoric acid must be used in pesticide products according to good manufacturing or good agricultural practices. The salts of phosphoric acid have low toxic potential. At this time, there is no concern for potential sensitivity to infants and children. A safety factor analysis has not been used to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

15. Environmental Fate and Ecotoxicity Assessment/Characterization:

In general, the constituents of the mineral acids, such as phosphoric acid, are commonly found in soil and water in the environment suggesting that releasing low levels of these chemicals would not normally be expected to adversely effect wildlife or water resources. Large releases may adversely affect wildlife and water resources either directly or indirectly. Direct effects may result from exceeding toxicity thresholds of specific chemicals. Indirect effects may be manifested through disrupting ecosystems through altering pH or increasing availability of algal nutrients.

Phosphoric acid is a medium strong acid. The magnitude of the pH changes, and thus the magnitude of effects, would depend on a number of factors including the amount of material

55977

released and the buffering capacity of the exposed soil or water. Normal aquatic pHs range from 5 to 9. EPA's Office of Water recommended water quality criteria for pH are 6.5 to 9 for freshwater and 6.5 to 8.5 for saltwater. At higher or lower pH aquatic life is expected to be adversely impacted. In addition, rapid changes in pH can also be detrimental to aquatic life. Phosphoric acid is not expected to be persistent in the environment. Instead it is expected to dissociate, react with organic or inorganic materials, and complex with ionic substrates.

The calcium, potassium, sodium, and zinc salts of phosphoric acid should dissociate in water resulting in a positively charged (cation) metal in solution. Dissociation is frequently dependent on pH, with lower (more acidic) pHs resulting in higher levels of dissociation and greater solubility. Aquatic toxicity of metals varies with the species of metal and its concentration. Zinc has recommended freshwater water quality criteria implying it is more toxic. Metals do not degrade and thus are permanent in the environment. They are likely to dissipate by being sequestered in soil, sediment, and plants.

Phosphorus containing chemicals are commonly used as fertilizers. They generally possess relatively low toxicity to terrestrial and aquatic organisms. As nutrients, they can cause increased plant growth which can be detrimental in aquatic ecosystems causing eutrophication. Eutrophication occurs when algae blooms die and are degraded by bacteria which drain oxygen from the water body. With the exception of tricalcium phosphate, all of these phosphorus containing chemicals are expected to be highly soluble. Phosphates tend to bind to soil reducing their tendency to overload aquatic systems. Ultimately, the salts of phosphoric acid are expected to be taken up and metabolized by plants to form naturally occurring compounds.

16. Cumulative Exposure:

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide chemical's residues and "other substances that have a common mechanism of toxicity." The chemicals considered in this document are structurally related; however, all of the salts are low toxicity chemicals. Therefore, the resultant risks separately and/or combined should also be low. EPA does not have, at this time, available data to determine whether these pesticide chemicals have a common mechanism of toxicity with other substances or how to include these pesticide chemicals in a cumulative risk assessment.

17. Determination of Safety:

Based on its review and evaluation of the available information, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to residues of phosphoric acid and its ammonium, sodium, potassium, calcium, magnesium, and zinc salts. Therefore, the following exemptions from the requirement of a tolerance are reassessed: In 40 CFR 180.1001 (c) calcium phosphate, disodium

phosphate, monoammonium phosphate, phosphoric acid, potassium phosphate, sodium acid pyrophosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate, tricalcium phosphate, and trisodium phosphate. In 40 CFR 180.1001 (d) ammonium polyphosphate, diammonium phosphate, potassium dihydrogen phosphate, sodium dihydrogen phosphate conforming to 21 CFR 182.6778, tetrapotassium pyrophosphate, and zinc orthophosphate. In 40 CFR 180.1001 (e) trisodium phosphate.

An exemption from the requirement of a tolerance can be established for magnesium phosphate given its use as surrogate data.

18. List Reclassifications:

The following List reclassifications are made or confirmed:

phosphoric acid: List 4B. With the restriction of use as a pH adjuster or buffer
calcium phosphate: List 4B
magnesium phosphate: List 4B
disodium phosphate: List 4B
monoammonium phosphate: List 4B
phosphoric acid, potassium phosphate: List 4B
sodium acid pyrophosphate: List 4B
sodium hexametaphosphate: List 4B
sodium tripolyphosphate: List 4B
tetrasodium pyrophosphate: List 4B
tricalcium phosphate: List 4B
trisodium phosphate: List 4B
ammonium polyphosphate: List 4B
diammonium phosphate: List 4B
potassium dihydrogen phosphate: List 4B
sodium dihydrogen phosphate conforming to 21 CFR 182.6778: List 4B
tetrapotassium pyrophosphate: List 4B
zinc orthophosphate: List 4B

The following table lists the various chemical names, CAS Reg. No., and CAS Index Names that will be used for listing in 40 CFR.180. Note that both the anhydrous and the hydrated forms are included. The Agency sees no reason to distinguish between these chemicals given that the only difference is the attachment of the water molecules.

Chemical Name	CAS. Reg. No.	Chemical Abstacts Index Name
phosphoric acid	7664-38-2	Phosphoric acid (7Cl, 8Cl, 9Cl)

Chemical Name	CAS. Reg. No.	Chemical Abstacts Index Name
monoammonium phosphate	7722-76-1	Phosphoric acid, monoammonium salt (8CI, 9CI)
diammonium phosphate	7783-28-0	Phosphoric acid, diammonium salt (8CI, 9CI)
tribasic ammonium phosphate	10361-65-6	Phosphoric acid, triammonium salt (8CI, 9CI)
ammonium hypophosphate (NH4)2H2P2O6	54390-90-8	Hypophosphoric acid, ammonium salt (9CI)
ammonium orthophosphate (NH4)3PO4 . 3H20	10124-31-9	Phosphoric acid, ammonium salt (8CI, 9CI)
ammonium polyphosphate	68333-79-9	Polyphosphoric acids, ammonium salts
calcium phosphate	10103-46-5	Phosphoric acid, calcium salt (8CI, 9CI)
calcium dihydrogen phosphate monohydrate	10031-30-8	Phnsphoric acid, calcium salt (2:1), monohydrate (8CI, 9Cl)
monbasic calcium phosphate	7758-23-8	Phosphoric acid, calcium salt (2:1) (8CI, 9CI)
dibasic calcium phosphate	7757-93-9	Phosphoric acid, calcium salt (1:1) (8CI, 9CI)
tribasic calcium phosphate	7758-87-4	Phosphoric acid, calcium salt (2:3) (8CI, 9CI)
calcium hypophosphate Ca2P2O6 .2H20	75499-50-2	Hypophosphoric acid, calcium salt (9CI)
calcium metaphosphate Ca(PO3)2	13477-39-9	Metaphosphoric acid (HPO3), calcium salt (8CI, 9Cl)
calcium pyrophosphate Ca2P2O7	7790-76-3	Diphosphoric acid, calcium salt (1:2) (9CI)
magnesium orthophosphate Mg3(PO4)2	10043-83-1	Phosphoric acid, magnesium salt (8CI, 9CI)
magnesium phosphate, dibasic	7757-86-0	Phosphoric acid, magnesium salt (1:1) (8CI, 9CI)
magnesium phosphate, monobasic	13092-66-5	Phosphoric acid, magnesium salt (2:1) (8CI, 9CI)
magnesium phosphate, tribasic	7757-87-1	Phosphoric acid, magnesium salt (2:3) (8CI, 9CI)
potassium phosphate	7778-77-0	Phosphoric acid, monopotassium salt (8CI, 9CI)
potassium phosphate	7758-11-4	Phosphoric acid, dipotassium salt (8CI, 9CI)
potassium phosphate	7778-53-2	Phosphoric acid, tripotassium salt (8CI, 9Cl)
potassium dihydrogen phosphate	7778-77-0	Phosphoric acid, monopotassium salt (8CI, 9CI)

Chemical Name	CAS. Reg. No.	Chemical Abstacts Index Name
potassium orthophosphate di-H KH2PO4	89595-41-5	Phosphate, dihydrogen, monopotassium salt (9CI)
tetrapotassium pyrophosphate	7320-34-5	Diphosphoric acid, tetrapotassium salt (9CI)
sodium acid pyrophosphate	7758-16-9	Diphosphoric acid, disodium salt (9CI)
sodium dihydrogen phosphate	7558-80-7	Phosphoric acid, monosodium salt (8CI, 9CI)
sodium hypophosphate Na4P2O6 .10H2O	15537-82-3	Hypophosphoric acid, sodium salt (8CI, 9CI)
sodium orthophosphate Na3PO4 .12H2O	7632-05-5	Phosphoric acid, sodium salt (8CI, 9CI)
sodium pyrophosphate Na4P2O7	7722-88-5	Diphosphoric acid, tetrasodium salt (9CI)
disodium phosphate	7558-79-4	Phosphoric acid, disodium salt (8CI, 9CI)
trisodium phosphate	7601-54-9	Phosphoric acid, trisodium salt (8CI, 9CI)
zinc orthophosphate	7543-51-3	Phosphoric acid, zinc salt (2:3), tetrahydrate (8CI, 9CI)
zinc orthophosphate	7779-90-0	Phosphoric acid, zinc salt (2:3) (8CI, 9CI)
ammonium polyphosphate	68333-79-9	Polyphosphoric acids, ammonium salt
tetrapotassium pyrophosphate	7320-34-5	Diphosphoric acid, tetrapotassium salt (9CI)
sodium acid pyrophosphate	7758-16-9	Diphosphoric acid, disodium salt (9CI)
sodium hexametaphosphate	68915-31-1	Polyphosphoric acids, sodium salts
sodium hexametaphosphate	10124-56-8	Metaphosphoric acid (H6P6O18), hexasodium salt (8CI, 9CI)
sodium tripolyphosphate	7758-29-4	Triphosphoric acid, pentasodium salt (8CI, 9CI) (c)
tetrasodium pyrophosphate	7722-88-5	Diphosphoric acid, tetrasodium salt (9CI) (c)

Attachment:

EFED Review of Mineral Acids (Birchfield; May 7, 2002)

INERT INGREDIENT FOCUS GROUP

DECISION DOCUMENT for

Sulfuric Acid and Salts

Petition No.: no

Tolerance Reassessments?: yes

Chemical Category/Group: mineral acid and salts

The following describes the various ways that sulfuric acid and its salts are used.

Table 1: Use Pattern (pesticidal - inert ingredient)

Chemical Name	Inert PC Code	40 CFR 180.1001	Inert Use Pattern (Pesticidal)	Current Inert List
sulfuric acid	878001	(c)	0.1% of pesticide formulation; pH control agent	3
ammonium sulfate	805601	(c)	solid diluent, carrier	4B
ferric sulfate	900332	(c)	solid diluent, carrier	4B
magnesium sulfate	850503	(c)	solid diluent, carrier safener	4B
potassium sulfate	805603	(c)	solid diluent, carrier	4B
sodium sulfate	805604	(c), (e)	solid diluent, carrier	4B
sodium bisulfate	873201	(d)	acidifying/buffering agent	4B
zinc sulfate (basic and monohydrate)	889001 911567	(c), (c), (e)	coating agent solid diluent, carrier water repellent, dessicant	3

There is also a tolerance exemption for ferrous sulfate in 40 CFR 180.2.

The tolerance exemption for calcium sulfate (40 CFR 180.1001(e)) was reassessed in the IIFG Decision Document "Weathered Materials", dated January 31, 2002. It is classified as List 4A.

60 of 74

At this time, only sulfuric acid, ferrous sulfate monohydrate, ferric sulfate, sodium bisulfate, and zinc sulfate are used as active ingredients. There are no longer any EPA-registered active ingredient uses for any of the other above-listed sulfate salts.

Table 2: Use Pattern (pesticidal - active ingredient)

Chemical Name.	Active PC Code	40 CFR	Number of Products	Active Use Pattern (Pesticidal)
sulfuric acid	078001	180.1019	8	used to kill bacteria on potatoes, milking equipment and in food processing areas; as a dessicant
ferrous sulfate monohydrate		180.2	15	used to kill moss and algae on ornamentals and turf
ferric sulfate	034902	none	2	used to kill moss on ornamental lawns and turf
sodium bisulfate	073201	none	3	used to kill bacteria on poultry , in toilet bowls, and in air treatment
zinc sulfate monohydrate	527200	none	2	used to kill moss on wood and other surfaces

Table 3: Use Pattern (FDA GRAS):

Chemical	GRAS Citation	GRAS Uses
sulfuric acid	21 CFR 184.1095	pH control agent, processing aid
ammonium sulfate	21 CFR 184.1143	dough strengthener, firming agent, processing aid
ferrous sulfate	21 CFR 184.1315	nutrient supplements, processing aid, use in infant formula
ferric sulfate	21 CFR 184.1307	flavoring agent
magnesium sulfate	21 CFR 184.1443	flavor enhancer, nutrient supplement, processing aid
potassium sulfate	21 CFR 184.1643	flavoring agent and adjuvant
zinc sulfate	21 CFR 182.8997	(no limitations specified)

Sulfuric acid also has uses in food contact surface sanitizing solutions under 21 CFR 178.1010.

Table 4: Use Pattern (non-pesticidal)

Chemical	Uses
sulfuric acid	used in fertilizers, chemicals, dyes and pigments, etchant, alkylation catalyst, electroplating baths, iron and steel, rayon and film, industrial explosives, lab reagent, nonferrous metallurgy
ammonium sulfate	manufacture of ammonia alum; in the manufacture of hydrogen sulfide to free it from nitrogen oxides; analytical uses; freezing mixtures; flameproofing fabrics and paper; manufacture of viscose silk; tanning, galvanizing iron; in fractionation of proteins.
ferric sulfate	preparation of iron alums, other iron salts and pigments; coagulant in water purification and sewage treatment; aluminum etching; pickling stainless steel and copper; as mordant in textile dyeing and calico printing; soil conditioners; polymerization catalyst.
magnesium sulfate	also known as epsom salts; as a cathartic and analgesic in medicine; finishing agent for textiles; as water-correcting agent in brewing industry; component of fireproofing compositions, preservatives, tanning & coagulating agents; chemical intermediate for magnesium trisilicate; component of nickel baths for plating other metals; catalyst support for platinum in sulfuric acid production
potassium sulfate	fertilizer for chloride-sensitive crops (tobacco); accelerator in wallboard (construction industry); agent in manufacture of glass; cathartic in human medicine; water-corrective agent for foods (brewery water); setting-expansion control agent for dental materials
sodium sulfate	tanning; pharmaceuticals; freezing mixtures; laboratory reagent
zinc sulfate	zinc sulfate & hydrated lime, 8 lb of each to 100 gal of water, are used to prepare spray called zinc-lime which is the zinc equivalent of bordeaux mixt. Zinc-lime is used extensively for control of bacterial spot disease of peaches. depressant in froth flotation, eg, for lead-zinc ores; component of spinning bath in manufacturer of rayon; chemical intermediate for manufacture of lithopone (pigment), carbamate fungicides (zineb), zinc metal, other zinc compounds (zinc stearate); component of zinc plating baths; chemical for water treatment; component of cosmetics (skin fresheners); reagent for paper bleaching; in manufacter of glue; accelerating agent in dental impression material; agent in textile dyeing and printing; preservative for wood and hides; fireproofing agent

It should be noted that potassium sulfate has use as a fertilizer and sulfuric acid is used in the preparation of fertilizers. Plants need various elements (metals and non-metals) for proper growth. Especially for agricultural crops, plants are supplied these elements as part of chemical fertilizers. The most important elements for plant growth are nitrogen, phosphorus, and potassium. Other metals needed in the soil for plant up-take are calcium, magnesium, iron, and trace elements such as zinc. Potassium sulfate is intentionally added to growing agricultural crops as needed to promote plant growth.

62 FR
189

Assessment of Sulfuric Acid and its Salts

Sulfuric acid and its ammonium, sodium, potassium, calcium, magnesium, iron, and zinc salts are being assessed as a group due to their chemical similarities. Due to its acidic nature the toxicity of sulfuric acid will be different from those of the more neutral sulfate salts. However, these sulfate salts all contain the sulfate ion (as either HSO_4^{-1} or SO_4^{-2}), and thus share some common chemistries. A major focus of this assessment is the work previously performed by FDA in assessing the safety of these chemicals as food additives.

1. Physical/Chemical Properties:

The physical and chemical properties of sulfuric acid and its various salts are described in the May 7, 2002 EFED Assessment. See attached.

2. Information Sources:

The following information was used in performing this assessment: The available information consisted of information retrieved from various websites, such as,

- EPA (www.epa.gov),
- NIOSH, (www.cdc.gov/niosh/ipcsneng/neng1197.html), (www.cdc.gov/niosh/ipcsneng/neng0362.html), (www.cdc.gov/niosh/74-128.html) (www.cdc.gov/niosh/idlh/7664939.html)
- TOXNET (www.toxnet.nlm.nih.gov.)
- NTP (ntp-server.niehs.nih.gov/NewHomeRoc/9RoCFacts.html)
- WHO (www.inchem.org/documents/jecfa/jecmono/v05je83.htm) and (www.inchem.org/documents/jecfa/jecmono/40abcj43.htm)

Various FDA GRAS Assessments were used, as well as, the FAO/WHO Assessment for sodium sulfate.

3. NIOSH (National Institute for Occupational Safety and Health)

The NIOSH IDHL (immediately dangerous to life or health) Documentation and the International Chemical Safety Card for sulfuric acid indicate that it is a colorless, oily, odorless liquid. The IDHL is 15 mg/m^3. The TLV (Threshold Limit Value) is 1 mg/m^3 (TWA). Sulfuric acid reacts violently with water. It is corrosive to the skin and the respiratory tract, and on ingestion.

The NIOSH International Chemical Safety Card for magnesium sulfate indicates that a TLV has not been established. No effects were noted.

63878

4. Acid Characteristics

An acid is a substance that when dissolved in water yields H^+ ions. The increase of the concentration of the H^+ ions lowers the pH. Mineral acids contain a non-metal such as phosphorus, nitrogen, sulfur, or chlorine which may or may not be combined with oxygen. When combined with oxygen, these anions can be referred to as oxyanions. Strong acids are those acids that when dissolved completely transfer their H^+ ions to water. Sulfuric acid is an example of a strong acid.

5. Cations: Sodium, Potassium, Calcium, Magnesium, Iron, and Zinc

Generally, a salt of a strong acid, such as sulfuric acid, when dissolved in water, dissociates to yield the sulfate anion (an anion which is negatively charged) and a positively charged cation. In the human body, these salts tend to dissociate and thus, for the most part, react in the body as the anion and the cation.

Metals such as calcium, sodium, magnesium, potassium, iron and zinc are required for proper functioning of human biological systems. For risk assessment purposes an important feature of these metals is that overall the body does have an effective means of processing them. The primary means of exposure to these cations is ingestion. Four of the most common cations required for functioning of human biology are: sodium, potassium, calcium and magnesium. Chemically, sodium and potassium belong to the same chemical family: calcium and magnesium belong to a different chemical family.

Sodium:

The average human body burden of sodium is approximately 20 grams (g) for a 70 kilogram (kg) adult. The sodium cation is necessary for the nerves and muscles to function properly. It is the principal cation of extracellular fluid, and helps to maintain the body's water balance. These electrolytes, the electrically charged ions in the body fluids, consist to a great extent of sodium and potassium. There is no Recommended Dietary Allowance (RDA) for sodium.

Potassium:

The average human body burden of potassium is approximately 140 g for a 70 kg adult. The potassium cation is important in regulating blood pressure, regulating cellular water content, maintaining proper pH balance, and transmission of nerve impulses. It helps to regulate the electrical activity of the heart and muscles. The potassium RDA is 900 mg/day.

Calcium:

The average human body burden of calcium is approximately 1 kg for a 70 kg adult; or

1/70th of our weight is calcium. The calcium cation is necessary for bone and teeth formation. It is also important to the proper functioning of nerves, enzymes, and muscles, and plays a role in blood clotting and the maintenance of cell membranes. The RDAs for calcium are 1000 mg/day for adults aged 19 to 50 years and 1200 mg/day for individuals older than 50 years.

Magnesium:

The average human body burden of magnesium is approximately 20 g for a 70 kg adult. The magnesium cation is also used in building bones. It plays a role in releasing energy from muscles and regulating body temperature. The RDA for magnesium is 310 to 320 mg/day for adult females and 400 to 420 mg/day for adult males with the RDA increasing with increasing age.

Two common metal cations that are needed for functioning of human biology, but in smaller amounts often referred to as trace, are iron and zinc.

Iron:

The human body burden of iron is approximately 4.1 g for a 70 kg adult. Iron functions as a carrier of oxygen. The hemoglobin molecule in blood transports oxygen from the lungs to the cells. The myoglobin molecule supplies oxygen to muscle cells. Iron deficiency is characterized by anemia, stunted growth, fatigue, and lowered resistance to infection. The RDAs for iron are 10 mg/day [0.14 mg/kg/day for an adult (70 kg) male (25 to 50 years)] and 15 mg/day [0.25 for an adult (60 kg) female (19 to 50 years)]. Pregnant and nursing woman have increased requirements for iron.

Dietary iron is poorly absorbed. The intestinal mucosa is a limiting factor in iron absorption. Normal absorption is about 1 mg/day in an adult male, and about 1.4 mg/day in an adult female. Absorption occurs in the divalent (ferrous) form, which must then be oxidized to the trivalent (ferric) form for use. Acute toxicity of iron ingested from normal dietary sources has not been reported. However, death especially in young children has resulted from ingestion of large overdoses of medicinal iron. (doses ranging from 40 to 1600 mg/kg - average 900 mg/kg). It is noted that the iron from ferric salts is less well absorbed than that from ferrous salts.

Zinc:

The average human body burden of zinc is approximately 100 milligram (mg) for a 70 kg adult. The zinc cation is a component of many enzymes and therefore has substantial involvement in many metabolic processes. It also assists in wound healing, blood formation, and general growth and maintenance of the body's tissues. The RDAs for zinc are 15 mg/day [0.21 mg/kg/day for an adult (70 kg) male] and 12 mg/day [0.2 mg/kg/day for an adult (60 kg) female]. According to FDA, the average daily intake of zinc from food (including water) was

0.23 mg/kg/day in the early 1980s. Consuming too much zinc (i.e. , 10 to 15 times the RDA) can cause health concerns such as anemia, pancreatic and kidney effects, and certain developmental effects. Consuming too little zinc can cause loss of appetite , decreased sense of taste and smell, decreased immune function, slow wound healing, skin sores, and developmental effects.

6. Ammonium Salt:

Ammonium sulfate dissociates to the negative anion and the positively charged ammonium cation (NH_4^+). Humans cannot convert atmospheric nitrogen to any form that can be used as part of any of the various metabolic cycles. Therefore, reduced nitrogen (NH_4^+) has to enter the body from an outside source. These sources are the nitrogen-containing amino acids in protein which are consumed daily as part of the diet. Although the human body can produce some amino acids, ten amino acids are considered "essential" amino acids, i.e., they must be consumed in the diet.

Generally the body works to maintain a balance of nitrogen intake and nitrogen excretion. The estimated daily ammonia intake through food and drinking water is 18 mg. In contrast, 4000 mg of ammonia per day are produced endogenously in the human intestine.

Ammonia and the ammonium ion are integral components of normal human metabolic processes. Ammonia is released following deamination that occurs when protein is used by the body for energy production. The liver converts ammonia via the urea cycle into urea. According to FDA in the "Evaluation of the Health Aspects of Certain Ammonium Salts as Food Ingredients" (1974), "the normal liver so readily detoxifies ammonium ion from alimentary sources that blood concentrations of ammonium salts do not rise to the levels necessary to evoke toxic response." Approximately 80% of the body's excess nitrogen is eliminated through the kidneys as urea, approximately 25 to 30 grams per day.

7. Toxicological Profile Table

The Agency has not reviewed any of the toxicological studies in the following table for sulfuric acid or any of its salts. The reviews of these studies were obtained from Toxnet, as well as other government websites.

Table 5: Toxicological Profile

Chemical	Toxicity	Other Information
Sulfuric Acid	Solutions of greater than 10% are severely corrosive by all routes of exposure; Solutions of less than >10% are strong irritants; IARC: There is sufficient evidence that occupational exposure to strong-inorganic-acid mists containing sulfuric acid is carcinogenic; ATSDR: No significant developmental or reproductive effects in mice or rabbits exposed to 20 mg/m^3 sulfuric acid aerosols 7 hours per day on gestation days 6 to 15	CERCLA Reportable Quantity: greater than 1000 lb (454 kg); 1993 US production= 80.3 billion lbs;
Ammonium Sulfate	13 week oral in rats; doses 0, 0.38, 0.75, 1.5, 3.0%; NOEL = 1.5% in males (886 mg/kg/day), 3% in females (1975 mg/kg/day), (HDT)	
Ferric Sulfate	Irritant to skin, eyes and mucous membranes; Excessive iron intake may cause toxicity	Primary use is in waste water treatment;
Magnesium Sulfate	Cathartic; Massive doses may cause systemic toxicity primarily loss of fluid and electrolytes; Negative in Ames TA100, TA1535, TA98 with and without activation; Negative in *E.coli* with and without activiation; Lowest published oral toxic dose in humans: 428 mg/kg (m) 351 mg/kg(f); Changes in serum composition (f,m), muscle weakness (f,m), cardiac arrhythmias (f); Lowest published lethal dose in rats after oral exposure 5g/kg	US production $5.7x10^{11}$g (1985)

Potassium Sulfate	Saline cathartic; Systemic toxicity unlikely unless massive doses consumed; Toxicity results from excessive loss of fluid and electrolytes.	1985 US production $2x10^{11}$g; EPA Drinking Water standard: 250,000 ug/L sulfate ion
Sodium Sulfate	Mouse oral LD_{50} = 5989mg/kg; Non-toxic and non-irritating to skin and mucous membraoes; Saline cathartic; systemic toxicity unlikely unless massive doses consumed; Toxicity results from excessive loss of fluid and electrolytes; Negative in cell transformation (viral enhanced) in Syrian hamster embryo (SA7/SHE) cells; Positive in *Saccharomyces cerevisiae* reverse gene mutation assay	1993 US production 1.44billion lb; EPA Drinking Water standard: 250,000 ug/L sulfate ion
Zinc Sulfate	Irritating to skin, eyes and mucous membranes; Use as an emetic may result in hemolytic and renal toxicity; Ames negative in TA97, TA102 with and without activation with S-9; Negative in Cell transformation with Syrian hamster embryo cells; Negative in *Saccharomyces cerevisiae.*	Regulated by Clean Water Act; subject to effluent regulations: EPA DW 5000ug/L ; US production $3.5x10^{10}$g (1985)

RL 3 89

8. OPP REDs (Reregistration Eligibility Decision Document)

Mineral Acid RED

The following information on the acute toxicity of sulfuric acid was extracted from the 1993 Mineral Acid RED: The oral LD_{50} is 350 mg/kg, toxicity category II. The dermal LD_{50} is > 2000 mg/kg, toxicity category III. Sulfuric acid is toxicity category I for eye and dermal irritation. No other toxicological data were required based on the use patterns at the time of the issuance of the RED and the corrosiveness shown in the acute studies for dermal and eye irritation.

There was also information on the acute toxicity of sodium bisulfate in the 1993 RED: The oral LD_{50} is 3000 mg/kg, toxicity category III. The dermal LD_{50} is > 10,000 mg/kg, toxicity category III. Sodium bisulfate is toxicity category I for eye irritation, and toxicity category IV for dermal irritation. No other toxicological data were required based on the use patterns at the time of the issuance of the RED and the fact that it forms ubiquitous metabolic products, sodium and sulfate, that are of little toxicological concern.

Iron Salts RED

The Iron Salts RED (1993) contains toxicity information on ferric sulfate, ferrous sulfate monohydrate, and ferrous sulfate heptahydrate. The ferric sulfate oral LD_{50} is 1487 to 2101 mg/kg, toxicity category III. The dermal LD_{50} is > 2000 mg/kg, toxicity category III. The inhalation LC_{50} is > 1.1 mg/L, toxicity category III. Ferric sulfate is toxicity category I for eye irritation and toxicity category IV for dermal irritation. For ferrous sulfate heptahydrate the LD_{50} is 1520 mg/kg. A sensitization study with ferric and ferrous sulfate found no indication of contact sensitization by this compound.

According to the RED, a "mutagenicity study in *E. coli* reported positive results at 30 umol/L. With due regard for the continuing exposure that human beings have had to the iron and sulfate components of these chemicals over many generation, it is considered unlikely that this reported result in microorganisms has any bearing on probable effects in humans or other mammals at the levels expected from use of these compounds as pesticides."

Zinc Salts RED

The following information on the acute toxicity of zinc sulfate was extracted from the 1992 Zinc Salts RED: The oral LD_{50} is > 2949 mg/kg, toxicity category III. Zinc sulfate acid is classified as toxicity category I for eye irritation based on one study in which "severe irritation was found when 0.09 g of 99% zinc sulfate was applied to rabbit eyes. In another study, the application of 420 ug zinc sulfate to the rabbit eye found moderate irritation." Zinc sulfate is toxicity category IV for dermal irritation (very slight irritation).

In a chronic study, "zinc sulfate caused hematological changes in rats and dogs fed about 100 ppm in the diet. ... In another report, mice given up to 5000 ppm of zinc as zinc sulfate in drinking water showed no evidence of carcinogenicity and no differences between treated and control groups."

"When rats were given 333 mg/kg zinc sulfate orally on days 1-18 of pregnancy, there was post-implantation mortality. Teratologic studies with oral zinc sulfate in three species of animals were negative for effects on pregnancy, maternal or fetal survival, or abnormalities. In these studies mice were given up to 30 mg/kg/day for days 6-15 of gestation, rats were given up to 42.5 mg/kg/day for days 6-15 of gestation, and hamsters were given up to 88 mg/kg/day for days 6-10 of gestation.

According to the RED, "[p]ositive results have been seen with zinc sulfate in some studies, including a *Drosophila melanogaster* sex chromosome assay with an oral 5 mmol/L dose and a mutation assay with *Saccharomyces cerevisiae* at 100 mmol/L. DNA inhibition was seen in human HeLa cells at 1 umol/L/4 hours and oncogenic transformation occurred at 200 umol/L with hamster embryo."

It was concluded that: "Although some positive mutagenicity studies have been reported, there is no indication of mutagenic effects in normal living organisms from everyday exposure. Living organisms have long been exposed to the components of zinc [sulfate] without such exposure being attributed to mutagenicity."

9. FDA GRAS (Generally Recognized As Safe) Assessments

Ammonium Sulfate

In the FDA Assessment titled "Evaluation of the Health Aspects of Certain Ammonium Salts as Food Ingredients" (1974), the following general conclusion on ammonium compounds was reached:

> "Ammonia and ammonium ion are integral components of normal metabolic processes and play an essential role in the physiology of man. Although there have been no significant feeding studies specifically designed to ascertain the safety threshold of ammonium compounds as food ingredients, numerous metabolic studies have been reported in the scientific literature. Extrapolation of these findings to the concentrations of ammonium compounds normally present in foods does not suggest that there would be untoward effects at such levels."

Ammonium sulfate was evaluated in the "FDA Assessment titled Evaluation of the Health Aspects of Sulfuric Acid and Sulfates as Food Ingredients." (1975) Ammonium sulfate has been used in food in the US since 1957. For infants (0 to 23 months) the average daily intake of ammonium sulfate in 1975 ranged from 0.53 to 2.58 mg/kg. For adults, it was 1.01

mg/kg.

Magnesium Sulfate

The FDA Assessment is titled "Evaluation of the Health Aspects of Magnesium Salts as Food Ingredients" (1976). Magnesium is (1) a dietary essential, (2) involved in many metabolic reactions, (3) important in electrolyte balance, and (4) present in fruits, vegetables, grains, milk, meat and fish. There are no chronic toxicity data. The "status of magnesium as a ubiquitous and essential dietary ingredient for the maintenance of homeostatic and bioenergetic mechanisms leads to the opinion that none of the available evidence suggests any probable hazard when any of the GRAS compounds of magnesium is used as a food ingredient." It was concluded that there was no available information on magnesium sulfate that "demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current and in the manner now practiced, or which might reasonably be expected in the future."

Potassium and Sodium Sulfate

The FDA Assessment is titled "Evaluation of the Health Aspects of Sulfuric Acid and Sulfates as Food Ingredients." (1975). For infants (0 to 23 months) the average daily intake of potassium sulfate in 1975 ranged from 0.05 to 0.49 mg/kg. For adults, it was 0.17 mg/kg. No information was given for sodium sulfate.

Sulfates are present in many foods. Several amino acids contain sulfur. "Sulfates are not rapidly absorbed from the gastrointestinal tract." In a metabolism studies in rats, mice and dogs, it was observed that most sulfate (in rats greater than 80%) was excreted in 24 hours, most of it in the urine.

> "Sulfates are natural constituents of foods and normal products of sulfur metabolism in animals.....it is evident that the toxic manifestations following oral administration of the sulfates considered in this report appear only at levels that are many times greater than those to which man is exposed in his daily diet." It was concluded that: "There is no evidence in the available information on sulfuric acid, and on ammonium, calcium, potassium, and sodium sulfates that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or that might reasonably be expected in future."

Zinc Sulfate

In the "GRAS (Generally Recognized As Safe) Food Ingredients - Zinc Salts" document (1972), the available information related to the safety of zinc sulfate as a food ingredient is summarized. However, the document offered no conclusions.

10. FAO/WHO Expert Committee on Food Additives

WHO performed an assessment on sodium sulfate in 2000. This assessment references an evaluation of the sulfate ion at the twenty-ninth meeting (Annex 1, reference 70). At that time an ADI of "not specified" was established based on the fact that "sulfate is a natural constituent of food and is a product of sulfur metabolism in animals." Sodium sulfate was not included in that ADI: at the time, there was no information to indicate the sodium sulfate was being used as a food-grade material.

Various studies were described including those on renal clearance and laxative trials in humans, and long-term and developmental studies in mice. It was concluded:

> "...that the results of the published studies in experimental animals do not raise concern about the toxicity of sodium sulfate. The compound has a laxative action, which is the basis for its clinical use. The minor adverse effects reported after use of ingested purgative preparations containing sodium sulfate may not be due to the sodium sulfate itself.
>
> In the absence of any evidence of toxicity, the Committee allocated a temporary ADI 'not specified'.....The ADI was made temporary because no information was available on the functional effect and actual uses of sodium sulfate in foods."

11. Human Health Hazard Characterization:

Sulfuric acid in its concentrated form is highly corrosive. Due to this property toxicity testing can only be performed on dilute concentrations or on neutralized forms of the acid such as a salt. The consequences of acute exposure to sulfuric acid are well-understood. "Concentrated sulfuric acid has an extremely irritant, corrosive, and destructive action on all living matter including human tissues, not by virtue of its acidity (in concentrated form it is only slightly ionized) but because of its affinity for water. The affinity is so strong that it will remove the elements of water from even anhydrous organic matter such as carbohydrates, resulting in charring or carbonization with the liberation of heat. In sulfuric acid splashing accidents, the heat liberated by dilution of the concentrated acid with water used to flush the affected areas, can add thermal burn to chemical injury of the body." Thus sulfuric acid "can burn and char the skin. It is even more rapidly injurious to the mucous membranes, and exceedingly dangerous to the eyes. Dilute sulfuric acid, while it does not possess this charring property, irritates the skin and mucous membranes by virtue of its acidity and can cause dermatitis."

Exposure to a mist of sulfuric acid can cause irritant effects on the mucous membranes and chemical corrosive effects upon the teeth. Strong inorganic acid mists containing sulfuric acid are listed as known human carcinogens.

Exposure to sulfuric acid in pesticide products as an inert ingredient would be in the role of a pH adjuster, that is, a liquid form, not a mist. This is indicative of the use of small amounts of sulfuric acid that are incorporated in a pesticide product to lower the pH . After the pH adjustment is performed, the sulfuric acid would be neutralized. As an active ingredient sulfuric acid is subject to FIFRA registration requirements and various labeling language as specified in the RED (Reregistration Eligibility Decision). Sulfuric acid must be used and applied according to good manufacturing or good agricultural practices. However, there are no significant adverse effects, to the general public or any population subgroup from consumption of residues of sulfuric acid resulting from such uses.

As a group these salts of sulfuric acid constitute a group of chemicals with many uses including direct use in the food supply. The available toxicity data indicates that the human body metabolizes sulfate, ammonium, calcium, iron, magnesium, potassium, sodium and zinc ions through well-understood pathways. In fact, all are necessary human nutrients. Various salts of sulfuric acid have been used in the food supply for a number of years. There are no available data to indicate any significant adverse effects to the general public or any population subgroup from consumption of residues of the ammonium, calcium, iron, magnesium, potassium, sodium, and zinc salts of sulfuric acid resulting from pesticide product uses.

Given the long history of safe use, the available toxicity data, an understanding of the human body's ability to metabolize these chemicals, and the evaluations by FDA and WHO, the IIFG believes that ammonium, sodium, potassium, magnesium, calcium, iron, and zinc sulfate salts are of low oral toxicity.

12. Type of Risk Assessment/Risk Characterization:

The toxicity of these chemicals derives from the irritation and caustic effects; therefore, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate.

Given the widespread occurrence of sulfuric acid and its salts in the existing food supply, the amounts that can be applied to food as a result of a use in a pesticide product would not be expected to significantly increase the existing amounts in the food supply. There is no available information on any of the salts of sulfuric acid considered in this document indicative of a human health hazard resulting from the EPA-regulated uses as well as the FDA GRAS uses to the general public or any population subgroup. No additional information is needed to assess their safety.

13. Sensitivity of Infants and Children:

Due to its acidic nature, its corrosive potential, there is high acute toxicity for sulfuric acid. Sulfuric acid must be used in pesticide products according to good manufacturing or good

73-C 74

agricultural practices. The ammonium, sodium, potassium, magnesium, calcium, iron, and zinc salts of sulfuric acid have low toxic potential. At this time, there is no concern for potential sensitivity to infants and children. A safety factor analysis has not been used to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

14. Environmental Fate and Ecotoxicity Assessment/Characterization:

In general, the constituents of the mineral acids, such as sulfuric acid, are commonly found in soil and water in the environment suggesting that releasing low levels of these chemicals would not normally be expected to adversely effect wildlife or water resources. Large releases may adversely affect wildlife and water resources either directly or indirectly. Direct effects may result from exceeding toxicity thresholds of specific chemicals. Indirect effects may be manifested through disrupting ecosystems through altering pH or increasing availability of algal nutrients.

Sulfuric acid is a strong acid. The magnitude of the pH changes, and thus the magnitude of effects, would depend on a number of factors including the amount of material released and the buffering capacity of the exposed soil or water. Normal aquatic pHs range from 5 to 9. EPA's Office of Water recommended water quality criteria for pH are 6.5 to 9 for freshwater and 6.5 to 8.5 for saltwater. At higher or lower pH aquatic life is expected to be adversely impacted. In addition, rapid changes in pH can also be detrimental to aquatic life. Sulfuric acid is not expected to be persistent in the environment. Instead it is expected to dissociate, react with organic or inorganic materials, and complex with ionic substrates.

The magnesium, sodium, potassium, iron, and zinc salts of sulfuric acid should dissociate in water resulting in a positively charged (cation) metal in solution. Dissociation is frequently dependent on pH, with lower (more acidic) pHs resulting in higher levels of dissociation and greater solubility. Aquatic toxicity of metals varies with the species of metal and its concentration. EPA's freshwater water quality criteria for iron is 1 ppm implying relatively low toxicity. Zinc has recommended criteria implying these metals are more toxic. Metals do not degrade and thus are permanent in the environment. They are likely to dissipate by being sequestered in soil, sediment, and plants.

15. Cumulative Exposure:

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide chemical's residues and "other substances that have a common mechanism of toxicity." The chemicals considered in this document are structurally related; however, all of the salts are low toxicity chemicals. Therefore, the resultant risks separately and/or combined should also be low. EPA does not have, at this time, available data to determine whether these pesticide chemicals have a common mechanism of toxicity with other

substances or how to include these pesticide chemicals in a cumulative risk assessment.

16. Determination of Safety:

Based on its review and evaluation of the available information, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to residues of sulfuric acid and its ammonium, sodium, potassium, calcium, magnesium, iron, and zinc salts. Therefore, the following exemptions from the requirement of a tolerance are reassessed: In 40 CFR 180.2 ferrous sulfate. In 40 CFR 180.1001 (c) ammonium sulfate, ferric sulfate, magnesium sulfate, potassium sulfate, sodium sulfate, sulfuric acid, zinc sulfate (basic and monohydrate), and zinc sulfate (basic and monohydrate). In 40 CFR 180.1001 (d) sodium bisulfate. In 40 CFR 180.1001 (e) sodium sulfate and zinc sulfate (basic and monohydrate). Also sulfuric acid in 40 CFR 180.1019.

17. List Reclassifications:

The following List reclassifications are made or confirmed:

Sulfuric acid: List 4B. With the restriction of use as a pH control agent; current limitation remains in place
Ammonium sulfate: List 4B
Ferrous sulfate: List 4B
Ferric sulfate: List 4B
Magnesium sulfate: List 4A, given its neutral pH in solution
Potassium sulfate: List 4A, given its neutral pH in solution
Sodium sulfate: List 4A, given its neutral pH in solution
Sodium bisulfate: List 4B, given its acidic nature, similar to that of sulfuric acid
Zinc sulfate: List 4B

The following table lists the various chemical names, CAS Reg. No., and CAS Index Names that will be used for listing in 40 CFR.180. Note that both the anhydrous and the hydrated forms are included. The Agency sees no reason to distinguish between these chemicals given that the only difference is the attachment of the water molecules.

Chemical Name	CAS. Reg. No.	Chemical Abstacts Index Name
Sulfuric acid	7664-93-9	Sulfuric acid (8CI, 9CI)
Ammonium sulfate	7783-20-2	Sulfuric acid diammonium salt (8CI, 9CI)
Ammonium bisulfate	7803-63-6	Sulfuric acid, monoammonium salt (8CI, 9CI)
Calcium sulfate	7778-18-9	Sulfuric acid, calcium salt (1:1) (8CI, 9CI)

Chemical Name	CAS. Reg. No.	Chemical Abstacts Index Name
Calcium sulfate ½ hydrate (CaSO4 . 1/2H20)	10034-76-1	Sulfuric acid, calcium salt, hydrate (2:2:1) (9Cl)
Calcium sulfate dihydrate (CaSO4 . 2H20)	10101-41-4	Sulfuric acid, calcium salt (1:1), dihydrate (8Cl, 9Cl)
Ferric sulfate	10028-22-5	Sulfuric acid, iron(3+) salt (3:2) (8CI, 9CI)
Iron(II) sulfate	7720-78-7	Sulfuric acid, iron(2+) salt (1:1) (8CI, 9CI)
Iron(II) sulfate dihydrate	10028-21-4	Sulfuric acid, iron(2+) salt (1:1), dihydrate (9CI)
Iron (II) sulfate heptahydrate (FeSO4 . 7H20)	7782-63-0	Sulfuric acid, iron(2+) salt (1:1), heptahydrate (8CI, 9CI)
Iron (II) sulfate pentahydrate (FeSO4 . 5H20)	13450-80-1	Sulfuric acid, iron(2+) salt (1:1), pentahydrate (8CI, 9CI)
Iron (II) sulfate tetrahydrate (FeSO4 . 4H20)	20908-72-9	Sulfuric acid, iron(2+) salt (1:1), tetrahydrate (8CI, 9CI)
Iron (II) sulfate ennahydrate (FeSO4 . 9H20)	73248-92-7	Sulfuric acid, iron(2+) salt (1:1), nonahydrate (9CI)
Magnesium sulfate	7487-88-9	Sulfuric acid magnesium salt (1:1) (8CI, 9CI)
Magnesium sulfate heptahydrate (epsom salt) (MgSO4 . 7H2O)	10034-99-8	Sulfuric acid magnesium salt (1:1), heptahydrate (8CI, 9CI)
Magnesium sulfate monohydrate (MgSO4 . H2O)	14168-73-1	Sulfuric acid magnesium salt (1:1), monohydrate (8CI, 9CI)
Potassium pyrosulfate (K2S2O7)	7790-62-7	Disulfuric acid, dipotassium salt (9CI)
Potassium hydrogen sulfate (KHSO4)	7646-93-7	Sulfuric acid, monopotassium salt (8CI, 9CI)
Potassium sulfate	7778-80-5	Sulfuric acid dipotassium salt (8CI, 9CI)
Sodium sulfate	7757-82-6	Sulfuric acid disodium salt (8CI, 9CI)
Sodium sulfate decahydrate (Na2SO4 .10H2O)	7727-73-3	Sulfuric acid disodium salt, decahydrate (8Cl, 9CI)
Sodium sulfate heptahydrate (Na2SO4 .7H2O)	13472-39-4	Sulfuric acid disodium salt, heptahydrate (8CI, 9CI)

Chemical Name	CAS. Reg. No.	Chemical Abstacts Index Name
Sodium pyrosulfate {Na2S2O7}	13870-29-6	Disulfuric acid, disodium salt (9CI)
Sodium sulfate hydrogen monohydrate {NaHSO4 .H2O}	10034-88-5	Sulfuric acid, monosodium salt, monohydrate (8CI, 9CI)
Sodium bisulfate	7681-38-1	Sulfuric acid, monosodium salt (8CI, 9CI)
Zinc sulfate (basic and monohydrate)	68813-94-5	Sulfuric acid, zinc salt, basic (9CI)
	7446-19-7	Sulfuric acid, zinc salt (1:1), monohydrate (8CI, 9CI)
Zinc sulfate	7733-02-0	Sulfuric acid, zinc salt (1:1) (8CI, 9CI)
Zinc sulfate heptahydrate {ZnSO4 . 7H2O}	7446-20-0	Sulfuric acid, zinc salt (1:1), heptahydrate (8CI, 9CI)
Zinc sulfate hexahydrate	13986-24-8	Sulfuric acid, zinc salt (1:1), hexahydrate (8CI, 9CI)

Attachment:

EFED Review of Mineral Acids (Birchfield; May 7, 2002)

1706-EUN
Ian Blackwell to: jmann 02/04/2011 03:53 PM
Cc: Tracy Lantz

To: Juli Mann
Steptoe & Johnson

From: Ian Blackwell
US EPA/AD

Dear Juli,

I have begun work on your acute toxicity submission for 1706-EUN (D385696). You cite two documents that I cannot locate. Can you forward copies or internet links of these to me please?

- EPA-HQ-OPP-2009-1005-0003
- EPA-HQ-OPP-2002-0162-170

Thank You,
Ian Blackwell
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention (OCSPP)
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

This is letter #2

Fw: Ashland Inc. Additional Comments Regarding Registration Applications for Chlorourea Biocide

Joan Harrigan-Farrelly to: Dennis Edwards, Chris Kaczmarek, Melba Morrow, Tracy Lamz, Tim McMahon, Nader Elkassabany, Philip Ross 02/03/2011 05:25 PM

Cc: Jennifer Mclain

FYI

Can you believe it?
----- Forwarded by Joan Harrigan-Farrelly/DC/USEPA/US on 02/03/2011 05:02 PM -----

From:	"Karen M. Hansen" <KHansen@bdlaw.com>
To:	Joan Harrigan-Farrelly/DC/USEPA/US@EPA
Cc:	Steven Bradbury/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA, Rosemarie Kelley/DC/USEPA/US@EPA, Kim Wilson/DC/USEPA/US@EPA
Date:	02/03/2011 03:36 PM
Subject:	Ashland Inc. Additional Comments Regarding Registration Applications for Chlorourea Biocide

Dear Joan,

Attached please find further comments on the recent data submissions made by Nalco regarding its two unregistered biocides. The attached letter also requests that the Agency initiate its public transparency process with respect to the unregistered urea products. As Ashland has discussed with EPA, urea, when chemically reacted with sodium hypochlorite, generates the active ingredient chlorourea. Chlorourea has never been registered by EPA as a pesticide and has no known toxicological data. Data on urea will not address the unknown and unique risk issues associated with chlorourea. For these and other reasons, the Agency should follow its policy on providing for meaningful stages of public review and comment for these registration applications.

Ashland appreciates your prompt consideration of these comments and its request. We also remain interested in meeting with you as set forth in our letter dated January 19, 2011.

Thank you, and please let me know if you have any questions at this time.

Best regards,

Karen

Karen M. Hansen, Esq.
Beveridge & Diamond, PC
1350 I Street, NW, Suite 700
Washington, D.C. 20005
(202)-789-6056 Direct
(202) 789-6190 Fax
khansen@bdlaw.com
www.bdlaw.com

disclosure, copying, distribution or use of the contents of this message is prohibited. If you have received this e-mail in error, please notify us immediately at (202) 789-6000 or by e-mail reply and then immediately delete this message. Thank you.

2011-02-03 to OPP re Nalco Data Submissions.pdf

BEVERIDGE & DIAMOND PC

Karen M. Hansen
1350 I Street, N.W.
Suite 700
Washington, D.C. 20005-3311
Direct: (202) 789-6056
Fax: (202) 789-6190
khansen@bdlaw.com

February 3, 2011

VIA ELECTRONIC MAIL

Joan Harrigan-Farrelly
Director, Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
2777 South Crystal Dr., One Potomac Yard
Arlington, Virginia 22202

Re: Nalco Applications to Register Ammonium and Urea Biocides
Submitted On or Around December 23, 2010

Dear Ms. Harrigan-Farrelly:

I am writing on behalf of Ashland Inc. following the recent publication by the National Pesticide Information Retrieval System ("NPIRS") of limited public information in connection with the contents of applications submitted to EPA on or around December 23, 2010 in support of the registration of three new Nalco pesticide products ("60615," "60620," and "60630"). While complete information about Nalco's application packages is not yet publicly available, even a brief review of the NPIRS information reveals a number of apparent deficiencies in Nalco's data packages that reinforce Ashland's concerns first identified in our January 19, 2011 comments to EPA. In addition, and as we have commented to EPA previously, there is very little published and peer-reviewed scientific information about the possible effects of Nalco's in-situ generated chlorourea biocide on human health and the environment. This fact, along with Nalco's unilateral decision several years ago to introduce this unknown chemistry to the public without EPA review, highlights the need for EPA to follow its guidelines for transparency in pesticide regulation by making appropriate information about Nalco's applications available to the public for review and comment before EPA makes a final decision about whether and under what terms and conditions to approve the registration of Nalco's unregistered biocides.

A. **EPA Should Provide a Meaningful Opportunity for Public Review and Comment In Connection With Nalco's Applications for the First-Ever Pesticidal Use of Chlorourea.**

Nalco's pending application to register urea represents precisely the type of pesticide registration action for which the Agency has recently committed itself to reviewing with more open and thorough public participation.[1] Although urea by itself may not be a "new" active ingredient and its pesticidal activity may be relatively understood, urea is not the active biocide involved with Nalco's product. Therefore, existing information on urea is essentially irrelevant to EPA's required review of the actual active ingredient in this product, chlorourea. In particular, the chemical reaction of Nalco's urea products with sodium hypochlorite generates a new and distinct active biocide, chlorourea. *See, e.g.*, Nalco Patent Application for "60615" dated Aug. 2, 2007 at Para. 0028 (stating that "the active chloroureas that remain are more effective antimicrobials...").[2] Chlorourea has never been tested or evaluated by EPA in any context under FIFRA. No published toxicological data exist for chlorourea, and the open literature on chlorourea is relatively sparse.

This lack of data, from a scientific perspective, raises a red flag regarding the uncertainties associated with applying this chemistry, for both the real-world workplace exposures and any food-contact scenarios that might be relevant to the use of Nalco's product. Moreover, the urea/hypochlorite chemical reaction, if uncontrolled, creates hydrazine, a dangerous gas. EPA has never before reviewed the intended use of chlorourea as a biocide nor the controls necessary to prevent creation of hazardous gases with such a use.

In October 2009, OPP expressed its commitment to expanding the openness of the FIFRA registration process and began implementing a public participation process for certain registration actions, including applications for new active ingredients, certain first uses, and "other actions of significant interest." As EPA has explained, public input can help inform the risk assessment and risk management processes associated with registration, while aiding in understanding potential risks and benefits, contributing to meaningful protective measures, and improving the public dialogue on pesticide registration decisions. Along with publishing notice of receipt of an application, which EPA should certainly do with respect to Nalco's two long-unregistered products, consistent with its new registration transparency policy EPA should also open a public docket for the active ingredient chlorourea, and provide both an initial 30-day

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[1] *See* "Public Participation Process for Registration Actions," dated March 31, 2010 (available online at: http://www.epa.gov/pesticides/regulating/public-participation-process.html).

[2] *See also* Ashland's Feb. 16, 2010 Presentation to EPA, at Slide No. 13 (describing the reaction equilibrium for Nalco's urea product); Slide No. 16 (demonstrating that chlorourea is a primary oxidant species that reacts directly and not via reformation of hypochlorite); and Slide No. 18 (demonstrating that chlorourea is the biocidal active in "60615").

comment period and another 30-day comment period when the risk assessment and proposed decision have been completed and added to the docket.[3]

We do not know if EPA is considering Nalco's application for the registration of urea as one for a "new active ingredient," "first food use," "first outdoor use," or "first residential use" that would automatically trigger the Agency's transparency policy. Yet nothing is known about the toxicological profile of chlorourea, or the potential human and environmental exposures to this new biocidal chemical (including possible food-contact resulting from chlorourea residues in treated paper). Accordingly, public participation in the registration process for Nalco's urea products should be viewed by the Agency as at least as important as that for an application for a new active ingredient or any other new use. Public involvement would also be fully consistent with OPP's substantial efforts over the past year to ensure public participation as it reviewed basic regulatory decisions related to Nalco's unregistered urea and ammonium sulfate products under FIFRA – most notably through the opening of the public docket on May 19, 2010 and subsequent extension of that public comment period until September 2, 2010.[4]

B. Publicly Available Information Regarding Nalco's Data Submissions Suggest Serious Deficiencies That Prevent EPA From Proper Review as Required by FIFRA

Although NPIRS provides only a partial picture of Nalco's actual data packages submitted to EPA, the information that is currently publicly available suggests that Nalco's submissions do not adequately address even the subset of requirements identified in EPA's December 16, 2010 letter, let alone the full range of data requirements applicable to Nalco's products as described in Ashland's January 19, 2011 letter to OPP. We summarize some of the apparent deficiencies below.

(1) Nalco's 60615 urea product:

---

[3] EPA's public participation policy is distinct from the Agency's statutory obligation under FIFRA to publish notice of receipt of all of Nalco's applications to the extent that they each seek the registration of new biocidal uses. As neither urea nor ammonium sulfate have previously been registered by EPA for biocidal use under FIFRA, Nalco's applications "entail a changed use pattern" with respect to both active ingredients that obligate EPA pursuant to FIFRA Section 3(c)(4) to "promptly" publish notice of Nalco's applications in the Federal Registers and provide 30 days for comment by any interested persons. *See also* 40 C.F.R. § 152.102 (stating that EPA will issue a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use). As of this date, no such notice appears to have been published by EPA in connection with any of Nalco's recent applications related to its two unregistered biocides.

[4] *See, e.g.*, Email dated July 13, 2010 from M. Morrow (EPA) to Counsel for Buckman, Ashland, and Nalco (explaining that an extension to the comment period was warranted in order to ensure that "members of the public have sufficient time to review all pertinent information regarding the sale, distribution and use of ammonia and urea for/in the pulp and paper board industry").

Notwithstanding the fully unevaluated nature of chlorourea, Nalco's single substantive submission in connection with "60615" appears to be limited to a 13-page "EPI SUITE" screening report (MRID No. 48340707) that was apparently provided to EPA as a substitute for any actual laboratory data. It is unclear how Nalco's attempt to use "EPI SUITE" modeling in this case will fully address the requirements outlined in the Agency's December 16 letter and set forth in EPA's regulations. With a completely unknown active ingredient such as chlorourea, however, EPA should require the development and submittal of data, and not allow the use of modeling or waivers that may be appropriate in other circumstances, such as for products involving thoroughly reviewed chemistries.

There is no indication in the NPIRS summary that Nalco has submitted an activated sludge respiration study to determine the potential impacts of chlorourea on microorganisms found in biological wastewater treatment systems.

Finally, while the specific purpose of Nalco's 14-page "discussion of residue issues" is not obvious from the NPIRS summary, the pre-registration requirement is to obtain a formal food contact substance notification for chlorourea from FDA.

(2) Nalco's 60620 ammonium sulfate product:

Nalco's five-page acute toxicity submission prepared by Steptoe & Johnson (MRID No. 48340805) is unlikely to represent the six separate toxicity studies on the active ingredient and proposed product required by EPA in its December 16 letter.

Moreover, although Nalco appears to have submitted the three acute ecotoxicity studies (MRID Nos. 43840806, -807 and -809) identified by EPA, it is not clear from NPIRS whether the aquatic and fish toxicity data were conducted, as they must be, using chloramine (rather than ammonium sulfate) as the test substance.

Finally, Nalco does not appear to have submitted any of the three mutagenicity battery studies required in EPA's letter.

(3) Nalco's 60630 urea product:

Nalco's "60630" product appears in NPIRS to be supported only by product chemistry data at this time. It is unclear what, if any, connection this application may have to Nalco's 60620 urea product. However, the "60630" product also must independently meet all of FIFRA's data requirements for urea biocides.

* * * * *

Thank you for your prompt attention to these comments and our request for EPA to confirm that it will follow the Agency's transparency policy in conducting the FIFRA review of Nalco's chlorourea biocide. Please contact me if you have questions or would like to discuss any aspect of this letter.

Sincerely,

Karen M. Hansen

cc: S. Bradbury, Ph.D. (OPP)
R. Kelly (OECA)
K. Wilson (OECA)
P. Ross (OGC)

Agenda for new AI scoping meeting on Tuesday: Ammonium Sulfate and Urea

Tracy Lantz to: David Bays, Dennis Edwards, Earl Goad, Ian Blackwell, Karen Hicks, Melba Morrow, Nader Elkassabany, Najm Shamim, Nathan Mottl, Steve Malish, Timothy Dole, Velma Noble

01/31/2011 10:20 PM

Attached below is the agenda for our meeting on Tuesday from 3-4 PM in room 8671.
If you are teleworking tomorrow, please call in: 866 299 3188 code: [redacted].
[redacted].
I've already heard from Najm and Karen who will call in should there be freezing rain.
Dennis will be in the office no matter what the weather.

Agenda for 020111Nalco scoping mtg.doc

If I am not in the office tomorrow, you may reach me by e-mail (epa address) or phone prior to the meeting [redacted].)

Thanks

Tracy Lantz

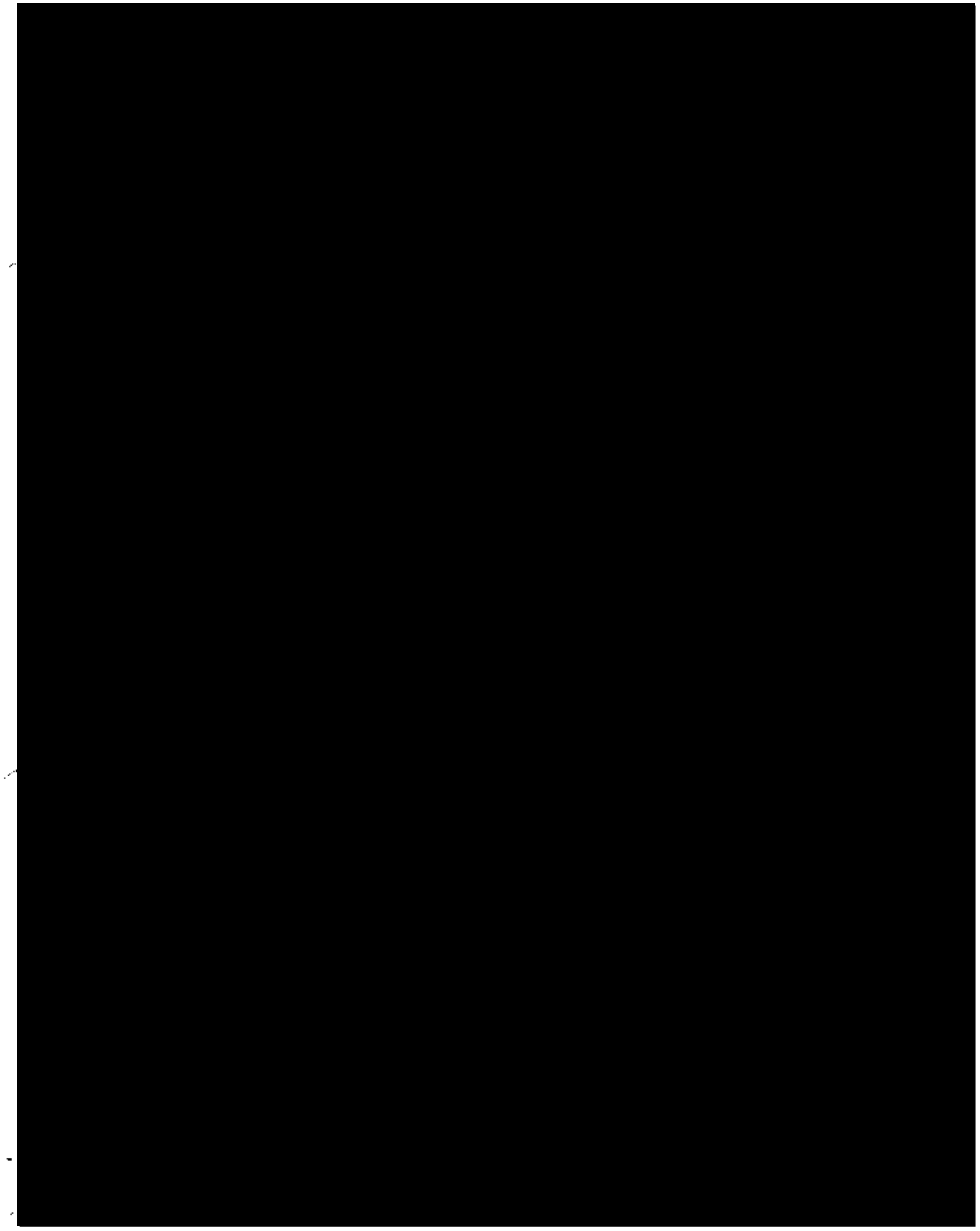
Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

Internal deliberative, *Personal privacy information*

Agenda
Nalco Scoping Meeting
New AIs: Ammonium Sulfate and Urea
2/1/11

[redacted]

Internal deliberative



Study Title

Nalco 60620 and Nalco 60615
Discussion of Residue Issues That May
Occur in Pulp and Paperboard

Robert Beckman opinion letter

Data Requirement

None

Author

Devon Wm. Hill

Submitter

Nalco Company
1601 West Diehl
Naperville, IL 60563

Report Completion Date
December 23, 2010

Report Number
N2010-Res

Total pages: 14
Study Report: 4
Confidential Appendix: 10

Statement of Data Confidentiality

Information claimed confidential on the basis of its falling within the scope of FIFRA § 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix and is cited by cross-reference in the body of the study.

Company: Nalco Company

Submitter Name: Linda J. Fane
Nalco Company

Signed: Linda J. Fane
Date: 12/23/2010

Good Laboratory Practices Statement

This paper, titled "Nalco 60620 and Nalco 60615: Discussion of Residue Issues That May Occur in Pulp and Paperboard" is a discussion and presentation of information. No data are being submitted that are subject to Good Laboratory Practice Standards (40 CFR Part 160).

Submitter: Linda Fane Date: 12/23/10

Linda Fane
Nalco Company

INTRODUCTION

This discussion of information is submitted to support the registration of Nalco 60620 and Nalco 60615. Information provided is to satisfy the Agency's request for residue studies to determine chloramine levels that may occur in pulp and paperboard.

The information has been removed to the confidential appendix and is cited by CROSS REFERENCE NUMBER 1, due to the confidential nature of the information.

CONFIDENTIAL APPENDIX
Study Title

Nalco 60620 and Nalco 60615
Discussion of Residue Issues That May Occur in Pulp and Paperboard

Data Requirement

None

Author

Devon Wm. Hill

Submitter

Nalco Company
1601 West Diehl
Naperville, IL 60563

Report Completion Date
December 23, 2010

Report Number
N2010-Res

Confidential Appendix: 10

Pages 221-229 - *Claimed confidential by submitter*

Replacement page for rainbow trout study
Mann, Juliana
to:
Tracy Lantz
01/13/2011 12:24 PM
Hide Details
From: "Mann, Juliana" <JMann@steptoe.com>

To: Tracy Lantz/DC/USEPA/US@EPA

1 Attachment

Nalco rainbow trout study pg2.pdf

Tracy:

A corrected page 2 for Nalco's rainbow trout study is attached. There was a problem with the Statement of No Data Confidentiality that has been corrected.

If you need anything else please let me know. Thank you for your help on this.

Juli

Juli Mann | Paralegal Specialist | Steptoe & Johnson LLP |1330 Connecticut Avenue, NW | Washington, DC 20036-1795 | Phone: 202-429-3095 | Fax: 202-429-3902 | jmann@steptoe.com

STEPTOE & JOHNSON LLP
ATTORNEYS AT LAW

WRITER'S DIRECT DIAL
202.429.3095
jmann@steptoe.com

1330 Connecticut Avenue, NW
Washington, DC 20036-1795
Tel 202.429.3000
Fax 202.429.3902
steptoe.com

January 10, 2011

Via U.S. MAIL

Mr. Dennis Edwards
Antimicrobials Division
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: Request for PRIA Fee Discretionary Refund

OPP Decision Number: D-443828

Product Name: Nalco 60620 (EPA File Symbol: 1706-EUN)

Dear Mr. Edwards:

On behalf of our client, Nalco Company, this is a request for a discretionary refund of the PRIA fee supporting the above identified pending registration. The assigned PRIA code, A380, carries a fee of $104,187 and a review time of 24 months.

We believe this fee and review time are not warranted for the following reasons:

1. Nalco 60620 is substantially similar to an existing registered product, Busan 1215, EPA Reg. No. 1448-433. That fact is substantiated by statements made by Buckman, registrant of Busan 1215 (attached to this request letter and available at EPA-HQ-OPP-2009-1005-0003 at electronic pages 4 and 7). Nalco believes that the correct identification of the active ingredient is ammonium sulfate, which is what is used to formulate this product. The Agency's review of the Buckman products is fully applicable to Nalco's product as Buckman identified its products to be essentially identical to Nalco's.

2. Nalco is relying upon existing Agency decisions regarding this compound and its dissociation products, which have been used to support multiple decisions. In particular, see the tolerance reassessment for mineral acids and associated salts (EPA-HQ-OPP-2002-0162-170), RED and registration review decision documents on mineral acids, decisions regarding related compounds such as ammonium nitrate (inert ingredient for food use), and decisions regarding ammonia and ammonium ion from similar compounds.

3. FDA determined that ammonium sulfate is a GRAS material when used as a direct food additive. *See* 21 CFR 184.1143.

4. The amount of data submitted to support the registration does not warrant a 24-month review time. In order to satisfy the product specific data requirements, Nalco submitted product chemistry and is relying on published literature and EPA/OPP assessments to satisfy acute toxicity data requirements. Nalco is relying on a selective cite-all to satisfy generic data requirements. Nalco submitted four ecotox studies, (OPPTS Guidelines 850.1010, 850.1075 (bluegill sunfish and rainbow trout), and 850.2100), and discussion papers on applicator exposure and residue. The submitted data are relatively simple, are acute studies, and require little time or effort to review. In fact, these are less complicated and shorter than typical efficacy studies submitted with other types of applications such as those under PRIA Code A570 (which has a PRIA fee in total of $3474).

The Agency will have little need to review data or conduct extensive assessments but rather will rely primarily on existing information and prior decisions. In accordance with the fee reduction guidance information to which you referred us, we believe the following to be the appropriate fee for this application (percentages are the percent of work by task):

Nonrefundable portion:	25%	$26,047
Review of new information	15.5%	$16,207
FR Notice	15%	$15,628
Total		$57,882

Based on the foregoing reasons, Nalco requests a fee reduction from $104,187 to $57,882. This amount was submitted to the Agency on December 22, 2010 to cover registration fees.

Thank you for your attention to this request. If you have any questions or require any additional information please contact me at (202) 429-3095.

Sincerely,

Juli Mann
Paralegal Specialist
Agent for Nalco Company

BUCKMAN LABORATORIES, INC.'S REPLY TO NALCO COMPANY'S DEC. 4, 2007 REQUEST THAT EPA RECONSIDER ITS REGISTRATION FOR AMMONIA PRODUCTS AS PRECURSORS TO CHLORAMINE USED IN WATER TREATMENT

AND

BUCKMAN LABORATORIES, INC.'S REQUEST THAT EPA IMMEDIATELY PROHIBIT FURTHER DISTRIBUTION AND SALE OF UNREGISTERED AMMONIA FOR WATER TREATMENT

Michael Boucher

McKenna Long & Aldridge LLP
1900 K Street, NW
Washington, D.C. 20006
(202) 496-7729

Counsel to

Buckman Laboratories, Inc.

September 2, 2008

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

I. Overview

Nalco Company's (hereinafter, "Nalco's") December 4, 2007 "Request That EPA Reconsider Its Registration for Ammonia Products as Precursors to Chloramine Used in Water Treatment and Provide Assurance That There Is No Risk of Enforcement during the Reconsideration and Any Necessary Transition Period" (hereinafter, "Nalco's Petition") is a tirade against EPA's registrations of BCMW (EPA Reg. No. 1448-432) and Busan 1215 (EPA Reg. No. 1448-433), Buckman Laboratories, Inc.'s (hereinafter, "Buckman's") manufacturing-use and end-use ammonia products, respectively. The violence of Nalco's protest tacitly acknowledges Nalco's need to register its own current end-use ammonia product, Nalcon 60620, because Nalcon 60620 and Busan 1215 essentially have the same composition, are used by the same industrial users in the same manner for water disinfection, and are considered interchangeable products in the marketplace. Nalco's Petition ignores the unknown and potentially unreasonable risks presented by the ongoing use of unregistered ammonia to produce monochloramine (hereinafter, "MCA"), including human health risks from unapproved residues of MCA in paper used for food packaging and toxicity to aquatic organisms from MCA residues in industrial waste water.[1] Not surprisingly, Nalco also ignores the significant and ongoing damage being done unfairly to the commercial value of Buckman's ammonia registrations – and to Buckman's ability to recoup its investment in such registrations – by Nalco's ongoing sale of unregistered ammonia with EPA's "temporary" permission, which has lengthened to seven months with no end in sight.

[1] Coincidentally, we have obtained a pre-publication *Federal Register* notice, attached hereto as Exhibit "A," which reports that Zentox Corporation has petitioned the Food and Drug Administration to use MCA as a food additive, specifically, "as an antimicrobial agent in poultry process chiller water" (emphasis added), even though EPA has not registered MCA or ammonia for any such use. This food additive petition underscores the urgent need for EPA to publicly affirm its jurisdiction over MCA – specifically, to prohibit the further distribution and sale of unregistered ammonia for *any* water treatment use, including poultry processing.

To justify the status quo, Nalco offers a series of increasingly erratic and unfocused arguments. Initially, Nalco alleges that ammonia cannot be registered, because it is not an active ingredient (Nalco's Petition at 6-7), but later flip-flops and acknowledges that, in fact, EPA can register a precursor of an active ingredient, where registration of the active ingredient itself is not practical (Nalco's Petition at 9) – exactly as EPA has done with BCMW and Busan 1215, because the registration of MCA itself for water treatment is impractical. Then, Nalco agrees that combining ammonia and sodium hypochlorite produces MCA (Nalco's Petition at 4), in a chemical reaction known since the early 1900s, but alleges that MCA is not an active ingredient that is separate from "chlorine" (hypochlorous acid) (Nalco's Petition at 8-9, 11), even though the production of MCA is a reaction that is not considered reversible (*i.e.*, once formed, MCA does not readily break down into, or otherwise produce, ammonia and hypochlorous acid/hypochlorite ions), and despite that EPA and industry recognize MCA as a distinct active ingredient with valuable properties that are different from those of hypochlorous acid. Nalco also plays variations on the foregoing theme, specifically, that ammonia "sequesters" and releases "chlorine" by a novel chemical process that Nalco never explains (Nalco's Petition at 4, 6-7, 11-12), and that ammonia is only an adjuvant used with "chlorine" and, thus, requires no registration (Nalco's Petition at 15), even though ammonia reacts completely with sodium hypochlorite to form a new active ingredient, MCA, and, thus, does not hold or release hypochlorous acid and does not resemble any adjuvant.

For the foregoing reasons, as articulated and explained in this petition, we respectfully request pursuant to section 553(e) of the Administrative Procedures Act (5 U.S.C. § 553(e)) that EPA deny Nalco's Petition and immediately prohibit further distribution and sale of unregistered ammonia for water treatment. Nalco has asked for time to register ammonia but neither needs

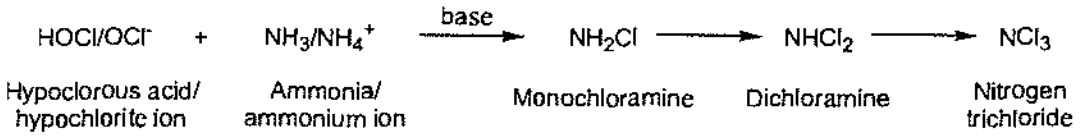
nor deserves any additional time. Nalco has had notice of EPA's policy on the registration of ammonia for water treatment since the Agency's registration of Buckman's ammonia products on March 6, 2007. Since then – a period of 18 months – Nalco has found ample time to make two lengthy and duplicative submissions and one responsive submission to EPA in order to subvert the Agency's registration of Buckman's ammonia products. Neither of Nalco's original filings ever had a likelihood, much less a *certainty*, of persuading EPA to revoke its considered registrations of ammonia, which Nalco knew at the time of its filings. Indeed, as recently as July 15, 2008, the Agency amended Buckman's registration of Busan 1215 to add a new use (industrial water systems), which suggests no intent by EPA to grant either of Nalco's original requests to revoke Buckman's ammonia registrations. Accordingly, in addition to filing petitions with EPA, Nalco also should have filed or, at a minimum, prepared itself fully to file an application to register ammonia sometime during the past 18 months. If, as it appears, Nalco has chosen instead to focus wholly on a speculative petition effort intended to manipulate EPA into allowing Nalco to remain on the market without an ammonia registration and, thereby, to continue to compete with Buckman unfairly and, specifically, to erode its customer base, the Agency should not now reward Nalco for its gamesmanship with any additional time to register ammonia.

In preparing this petition on behalf of Buckman, we consulted with scientists and regulatory consultants at Technology Sciences Group Inc., namely, Dr. Robert Stewart, Vice President and Managing Director, and Dr. David Brookman, Director of Environmental Chemistry. Drs. Stewart and Brookman have reviewed and concur in our technical representations in this petition.

II. **Both Nalco and Buckman sell ammonia for use in proprietary systems in which ammonia and sodium hypochlorite react to form MCA, which is the active ingredient supplied by each system for water treatment.**

Use of either Nalco's or Buckman's end-use ammonia product, as labeled, generates the same main active ingredient, MCA (monochloramine), which is formed by a chemical reaction that occurs at the time of use. The general reaction is as follows:

Figure 1



The reaction is normally terminated at the stage where MCA is formed, but dichloramine and nitrogen trichloride also may occur.

The nominal active ingredient in Nalco's end-use ammonia product (Nalcon 60620) is "ammonium sulfate" and in Buckman's end-use ammonia product (Busan 1215) is "ammonia (total)," which derives from an aqueous mixture of ammonia and ammonium sulfate. Therefore, both products provide ammonia or ammonium ions in the reaction shown in Figure 1 above, and both lead to the in-situ generation of one or more chloramines.

According to its label, attached hereto as Exhibit "B," Nalcon 60620 is an unregistered formulation consisting of 20% ammonium sulfate and 80% "constituents ineffective as spray adjuvants," presumably water. Nalco sells Nalcon 60620 as part of its "OxiPRO™ Deposit Control Technology" and, specifically, for use in Nalco's "OxiPRO Feed System," which is illustrated and described in a Nalco proposal and a Nalco slide presentation attached hereto as Exhibits "C" and "D," respectively. Nalco's label for Nalcon 60620 and Nalco's materials on the OxiPRO Feed System describe a process in which a Nalco technician adds Nalcon 60620 to

Fw: Ammonium Sulfate Docket Verification
Tracy Lantz to: Caroline Klos 01/07/2011 10:10 AM
Cc: Dennis Edwards, Velma Noble

with additional signature, see below.

Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

----- Forwarded by Tracy Lantz/DC/USEPA/US on 01/07/2011 10:09 AM -----

From:	cts/cts/QP/USEPA/US@EPA
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

gave copy to Steve M. on 1/26/11

December 9, 2005

Memorandum

Subject: Hazard Assessment for Ammonia and Monochloroamine

for 1796-EUN

Active Ingredient: Ammonia
PC Code 128824

DP Barcode: D313637

From: Deborah Smegal, MPH, Toxicologist
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Through: Norm Cook, Branch Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

To: Drusilla Copeland
Regulatory Management Branch I
Antimicrobials Division (7510C)

1.0 BACKGROUND

The Agency was requested to review a new use for ammonia for use in food-contact pulp/paper. The registrant proposes to mix their product BCMW/BUSAN 1215, which contains dilute solutions of ammonia, with sodium hypochlorite (12.5%) to form monochloramine on pulp/paper. Thus, this hazard assessment will evaluate both potential occupational exposure to ammonia and potential dietary exposures to monochloramine. Therefore, the toxicity profile for ammonia focuses on the hazard associated with dermal and inhalation exposures, while the toxicity profile for monochloramine focuses on the hazard associated with oral exposures.

12.5% to 20%

2.0 HAZARD ASSESSMENT

2.1 Acute Toxicity of BUSAN 1215

The acute toxicity data for the product BUSAN 1215 containing 7.59% are acceptable. All of the acute toxicity studies for BUSAN 1215 are listed in category IV, and it is a non-sensitizer. The acute toxicity data on the BUSAN 1215 is summarized below in Table 1.

Table 1. Acute Toxicity Data on Busan 1215

Guideline No./ Study Type	MRID No.	Results	Toxicity Category
870.1100 Acute oral toxicity	46435108	LD_{50} > 5000 mg/kg	IV
870.1200 Acute dermal toxicity	46435109	LD_{50} > 5000 mg/kg	IV
870.1300 Acute inhalation toxicity	46435110	LC50 ≥ 2.08 mg/L (4-hr)	IV
870.2400 Acute eye irritation	46435111	Minimally irritating (rabbit) Irritation cleared within 48 hours	IV
870.2500 Acute dermal irritation	46435112	Slightly irritating	IV
870.2600 Skin sensitization	46435113	Not a skin sensitizer (guinea pig)	

2.2. Ammonia Toxicity Profile

Ammonia is an essential mammalian metabolite for DNA, RNA and protein synthesis and is necessary for maintaining acid-base balance. It is produced and used endogenously in all mammalian species. Ammonia is excreted primarily as urea and urinary ammonium compounds through the kidneys (ATSDR 2004).

Acute. Ammonia is a corrosive substance and the main toxic effects are restricted to the sites of direct contact with ammonia (i.e., skin, eyes, respiratory tract, mouth, and digestive tract). It is an upper respiratory irritant in humans. The acute toxicity of gaseous ammonia is generally considered the effect of the chemical reactivity producing an extremely sharp, irritating odor

causing eye, skin, and respiratory irritation. At concentrations exceeding 50 ppm, immediate nose and throat irritation is experienced (ATSDR 2004). Immediate lethality may occur at concentrations in excess of 5,000 ppm; however, the acute lethal exposure concentration depends on the exposure duration (ATSDR 2004).

The skin is extremely sensitive to airborne ammonia or ammonia dissolved in water. Dermal exposures to liquid ammonia or concentrated solutions and/or ammonia gas are frequently occupationally related and produce cutaneous burns, blisters, and lesions of varying degrees of severity. The topical damage caused by ammonia is probably due mainly to its reactivity and irritation properties. Its high water solubility allows it to dissolve in moisture on these surfaces, react with fatty substances, be absorbed into deeper layers, and inflict extensive damage. The severity of the damage is proportional to the concentration and duration of exposure; flushing with water immediately after contact alleviates or prevents effects (ATSDR 2004).

Ingestion of concentrated ammonium solutions may produce severe burns and hemorrhage of the upper gastrointestinal tract (ATSDR 2004).

Subchronic. Ammonia causes adverse respiratory effects in animals following inhalation exposure. Below are summaries of several inhalation toxicity studies presented in USEPA (2005a).

Broderson et al. (1976) exposed groups of F344 rats (6/sex/dose) continuously to 25, 50, 150 or 250 ppm ammonia (HEC = 1.9, 3.7, 11.2 or 18.6 mg/cu.m, respectively) for 7 days prior to inoculation with Mycoplasma pulmonis and from 28-42 days following M. pulmonis exposure. Each treatment group had a corresponding control group exposed only to background ammonia and inoculated with M. pulmonis in order to produce murine respiratory mycoplasmosis (MRM). The following parameters were used to assess toxicity: clinical observations and histopathological examination of nasal passages, middle ear, trachea, lungs, liver and kidneys. All levels of ammonia, whether produced naturally or derived from a purified source, significantly increased the severity of rhinitis, otitis media, tracheitis and pneumonia characteristic of M. pulmonis. Furthermore, there was a significant concentration response between observed respiratory lesions and increasing environmental ammonia concentration for gross and microscopic lesions. All lesions observed were characteristic of MRM. Gross bronchiectasis and/or pulmonary abscesses and the extent of gross atelectasis and consolidation was consistently more prevalent in exposed animals at all concentrations than in their corresponding controls. The severity of the microscopic lesions in the nasal passages, middle ears, tracheas and lungs was significantly greater in all exposed groups compared with controls. Increasing ammonia concentration was not associated with an increasing frequency of M. pulmonis isolations. Additionally, rats not exposed to M. pulmonis and exposed to ammonia at 250 ppm developed nasal lesions (epithelial thickening and epithelial hyperplasia) unlike those observed in inoculated rats. Based upon these data in M. pulmonis exposed rats, a LOAEL(HEC) of 1.9 mg/cu.m was identified.

Gamble and Clough (1976) whole-body exposed female Porton rats to ammonia concentrations of 200 (+/- 50) ppm for 4, 8 or 12 days or 435 (+/- 135) ppm for 7 days. Duration of exposure was not otherwise specified. The total number of animals was 16, but the apportionment into

exposure groups was not provided. Hyperplasia of the tracheal epithelium was shown to be concentration- and time-dependent. At 4 days of exposure to 200 ppm, the epithelium had changed to transitional-stratified and by 8 days there was gross change: disappearance of cilia and stratification increasing to folds forming on the luminal surface. A mucilaginous exudate was also evident with a slight increase in submucosal cellularity. At 12 days at the 200 ppm concentration, the epithelialization had increased in thickness. Rats exposed for 7 days to 435 ppm showed acute inflammatory reactions with infiltration of neutrophils, large mononucleated cells, monocytes and immature fibroblasts in the trachea. Evidence of necrotic changes at the luminal surface included pyknotic nuclei and karyorrhectic cells.

Groups of 10 guinea pigs and 20 Swiss albino mice were exposed continuously to an ammonia-air concentration of 20 ppm (13.9 mg/cu.m) for up to 6 weeks. A separate group of six guinea pigs was similarly exposed to an ammonia concentration of 50 ppm (35 mg/cu.m) for 6 weeks, and a group of 21 Leghorn chickens was exposed to a 20 ppm concentration for up to 12 weeks. Controls (number not specified) were maintained under identical conditions, except for the ammonia. Smaller groups of chickens were exposed continually to either 200 ppm for up to 3 weeks or 1000 ppm for up to 2 weeks. The effects of ammonia were found to be both time- and concentration-dependent. While no effects were observed in guinea pigs, mice, or chickens sacrificed after 1, 2, 3 or 4 weeks of exposure at 20 ppm, darkening/reddening, edema, congestion, and hemorrhage were seen in the lungs of all three species at sacrifice after 6 weeks of exposure at that concentration. In guinea pigs exposed to 50 ppm ammonia for 6 weeks, grossly enlarged and congested spleens, congested livers and lungs, and pulmonary edema were seen. In chickens exposed to 200 ppm for 17-21 days, liver congestion and slight clouding of the cornea were observed in addition to those effects observed in the chickens exposed to 20 ppm ammonia for 6 weeks. At 1000 ppm, the same effects, in addition to congestion of the spleen, were seen in chickens after just 2 weeks of exposure, and corneal opacities developed within just 8 days of exposure. In a second series of experiments, it was found that a 72-hour exposure to 20 ppm ammonia significantly increased the infection rate of chickens subsequently exposed to an aerosol of Newcastle disease virus, while the same effect was observed in just 48 hours in chickens exposed to 50 ppm. Changes in gross and micropathology did not accompany the change in disease rate (Anderson et al., 1964).

Guinea pigs were exposed to 0 or 170 ppm (118 mg/cu.m) 6 hours/day, 5 days/week for up to 18 weeks. No adverse effects were observed in animals exposed to ammonia for 6-12 weeks (HEC=21 mg/cu.m). Mild changes in the spleen, kidney suprarenal glands and livers were observed (HEC=19 mg/cu.m) in guinea pigs exposed for 18 weeks. No effects on the lungs were observed. The upper respiratory tract was not examined (Weatherby, 1952).

Swiss-Webster mice (16-24/group) were exposed to 0 or 305 ppm ammonia (212 mg/cu.m) 6 hours/day for 5 days. Nasal lesions were observed at 212 mg/cu.m which when dose duration adjusted for the RGDR, equals a LOAEL(HEC) of 4.5 mg/cu.m (Buckley et al., 1984).

Continuous exposure of rats to ammonia at 0, 40, 127, 262, 455 or 470 mg/cu.m for a minimum of 90 days (114 days for the 40 mg/cu.m group) was conducted in male and female Sprague-Dawley and Long-Evans rats. A LOAEL of 262 mg/cu.m (HEC=28 mg/cu.m) was determined based upon nasal discharge in 25% of the rats, and nonspecific circulatory and degenerative

changes in the lungs and kidneys that were difficult to relate specifically to ammonia inhalation. A frank-effect-level of 455 mg/cu.m (HEC=48.7 mg/cu.m) was observed due to high mortality in the rats (90-98%). Nasal passages were not histologically examined (Coon et al., 1970).

Duroc pigs were exposed to ammonia concentrations of 10, 50, 100 and 150 ppm. Exposure to ammonia significantly decreased both food intake and body weight gain. Higher concentrations caused nasal, lacrimal and mouth secretions, which became less severe over time. No treatment-related gross or microscopic changes were observed in the bronchi, lungs or turbinates at necropsy (Stombaugh et al., 1969).

Various animal species were exposed to 0, 155 and 770 mg/cu.m for 8 hours/day, 5 days/week for 30 exposures (rats, guinea pigs, rabbits, dogs and monkeys). The LOAEL for lung inflammation is 770 mg/cu.m for rats (HEC=82.4 mg/cu.m) and guinea pigs. Ocular and nasal irritation was observed at 770 mg/cu.m in rabbits and dogs. The upper respiratory tract was not examined (Coon et al., 1970).

Developmental/Reproductive. No developmental or reproductive studies have been conducted by the registrant for ammonia.

Neurotoxicity. No neurotoxicity studies have been conducted by the registrant. Studies in the scientific literature indicate that neurological effects have been observed in humans following inhalation and dermal exposure. These effects have been limited to blurred vision, most likely due to direct contact, but more severe exposures, which result in significant elevation of blood ammonia levels (hyperammonemia) can result in diffuse nonspecific encepthalopathy, muscle weakness, decreased deep tendon reflexes and loss of consciousness (ATSDR 2004).

Cerebral edema and herniation and intracranial hypertension have been noted in animal models of hyperammonemia. The mechanism of ammonia-induced encephalopathies has not been definitively elucidated. It is thought to involve the alteration of glutamate metabolism in the brain with resultant increased activation of N-methyl-D-aspartate (NMDA) receptors, which causes decreased protein kinase C-mediated phosphorylation of Na+/K+ ATPase, and depletion of ATP. This reduced ATP level may be involved in ammonia-induced coma and death. A disruption in neurotransmission has also been suggested by alteration of brain tubulin, which is an essential component of the axonal transport system (ATSDR 2004).

Chronic. Chronic occupational exposure to low levels of airborne ammonia (< 25 ppm) had little effect on pulmonary function or odor sensitivity in workers at some factories, but studies of farmers exposed to ammonia and other pollutants in livestock buildings indicated an association between exposure to pollutants, including ammonia, and an increase in respiratory symptoms and/or decrease in lung function parameters. The contribution of ammonia to these respiratory symptoms is unclear (ATSDR 2004).

USEPA (2005a) established an inhalation reference concentration (RfC) based on both an epidemiological study and an animal toxicity study to be protective of respiratory effects. A no-observable-adverse effect level (NOAEL) of 6.3 mg/m^3 (9.2 ppm) from an occupational study

was combined with a lowest observable adverse effect level (LOAEL) of 17.5 mg/m^3 (25 ppm), which has a human equivalent concentration (HEC) of 1.9 mg/m^3, for respiratory effects in a rat subchronic inhalation study. The Agency acknowledges that there is a lack of adequate reproductive and developmental toxicology studies for ammonia in the IRIS record (USEPA 2005a), and applied an additional 3X factor to account for these deficiencies. Based on the proposed use pattern, BCMW/BUSAN 1215 containing dilute solutions of ammonia is mixed with sodium hypochlorite (12.5%) to form monochloramine in pulp/paper. Because there is no concern for potential dietary exposure to ammonia for this proposed use pattern, it is not necessary to consider the FQPA safety factor for ammonia. However, the Agency believes the FQPA factor should be considered for the potential dietary exposures to monochloramine (see below).

Mutagenicity/Carcinogenicity. There is no evidence that ammonia causes cancer. Ammonia has not been classified for carcinogenic effects by EPA, the Department of Health and Human Services (DHHS), or the International Agency for Research on Cancer (IARC) (ATSDR 2004).

There are a few studies on the genotoxicity of ammonia. Overall, these studies suggest that ammonia and ammonia ion may have clastogenic and mutagenic properties. One study evaluated blood samples from 22 workers exposed to ammonia in a fertilizer factory and 42 control workers not exposed, and found an increased frequency of chromosomal aberrations (CAs) and sister chromatid exchanges (SCEs), increased mitotic index (MI) and increased frequency of CAs and SCEs with increasing length of exposure (Yadav and Kaushik 1997 as cited in ATSDR 2004). An increased frequency of micronuclei compared to controls was noted in mice administered ammonium intraperitoneally (Yadav and Kaushik 1997 as cited in ATSDR 2004). There were positive effects in a reverse mutation test in E. coli, but only in treatments using toxic levels of NH_4+ (98% lethality). Another study found slight mutagenic activity in *Drosophila* following exposure to ammonia gas, but at toxic levels (survival after treatment was <2%). *In vitro* tests of chick fibroblast cells showed that buffered ammonia-ammonium chloride solutions can induce clumping of chromosomes, inhibit spindle formation and result in polyploidy (Rosenfeld 1932 as cited in ATSDR 2004). Reduced cell division was noted in mouse fibroblasts cultured in media to which ammonia and ammonium chloride were added (Visek et al. 1972 as cited in ATSDR 2004).

2.3 Monochloramine Toxicity Profile

Developmental/reproductive. The developmental and reproductive toxicity of monochloramine has been examined in rats, but with suboptimal studies. However, due to the chemical relationship between monochloramine and chlorine, the Agency believes that the reproductive and developmental studies for chlorine may be used to satisfy these data gaps for monochloramine. The available studies do not indicate concerns for increased sensitivity of the fetus or offspring. Thus, the Agency believes it is appropriate to reduce the FQPA factor to 1X for monochloramine. Below are summaries of reproductive and developmental studies.

In a reproductive study by Carlton et al. (1986), chloramine was administered by gavage in deionized water at doses of 0, 2.5, 5.0 and 10 mg chloramine/kg/day to male (12/dose group) and female (24/dose group) Long Evans rats for a total of 66-76 days. Males were treated for 56 days

and females for 14 days prior to mating. Dosing continued during the 10-day mating period and afterwards females were dosed with chloramine daily during gestation and lactation. Males were necropsied at the end of the mating period. Dams and some offspring were necropsied at 21 days after birth. Other offspring were dosed with chloramine after weaning until they were 28-40 days old. No statistical differences were observed between control and exposed rats in fertility, viability, litter size, day of eye opening or average day of vaginal patency. There were no alterations in sperm count, direct progressive sperm movement, percent mobility or sperm morphology in adult males. Weights of male and female reproductive organs were not significantly different among control and test groups, and there were no significant morbid anatomic changes evident on tissue examination. There were no signs of toxicity, changes in blood counts, or effects on body weight in adult rats of either sex at any dose level. The mean weight of the pups was not affected by chloramine treatment. A NOAEL of 10 mg/kg-day for reproductive effects can be defined from this study.

Abdel-Rahman et al. (1982) administered monochloramine in the drinking water to female Sprague-Dawley rats (6/dose group) at 0, 1, 10 and 100 mg/L for 2.5 months prior to and throughout gestation. By using body weights provided by the investigators and a reference water consumption value (U.S. EPA, 1987), the intake of monochloramine was estimated to be to 0, 0.15, 1.5 and 15 mg monochloramine/kg/day. Treatment with monochloramine did not increase the number of fetal resorptions or affect fetal weight. In addition, monochloramine did not induce soft-tissue anomalies or skeletal malformations. A developmental NOAEL of 15 mg monochloramine/kg/day is provided by this study, although confidence is low due to the small number of animals exposed.

Chronic. The long-term effects of chloraminated water were examined in rats and mice (NTP 1992). In both species, there were no statistically significant findings attributable to chemical exposure at the highest dose tested of 200 ppm chloramine, or 9.5 mg chloramine/kg/day for rats and 17.2 mg chloramine/kg/day for mice. The NOAEL of 9.5 mg chloramine/kg/day in rats is chosen as the basis for the chronic oral RfD by USEPA (2005b). Although a higher NOAEL in the study of 17.2 mg/kg-day is found for mice, rats may be the more sensitive species since doses between 9.5 and 17.2 mg/kg-day were not tested in rats.

Mutagenicity/Carcinogenicity. Monochloramine is not classifiable as to human carcinogenicity (Group D) based on inadequate human data and equivocal evidence of carcinogenicity from animal bioassays. A two-year bioassay showed marginal increase in mononuclear cell leukemia in female F344/N rats. No evidence of carcinogenic activity was reported in male rats or in male or female B6C3F1 mice. Genotoxcity studies, both in vitro and in vivo, gave negative results (USEPA 2005b).

3.0 TOXICITY ENDPOINT SELECTION

Tables 2 and 3 present a summary of the recommended toxicity endpoints for ammonia and monochloramine, respectively to be used in the risk assessment.

A. Occupational Exposure to Ammonia

A.1 Dermal Exposure (All durations).

No endpoint was selected because the labels will specify the use of gloves, full body clothing and eye protection. Thus, there is no potential for dermal exposure.

A.2 Inhalation Exposure (All durations)

Study Selected: Holness et al. (1989) epidemiological study of workers

Executive Summary: Holness et al. (1989) investigated production workers exposed to ammonia in a soda ash facility. All of the available 64 production workers were invited to participate and 82% agreed to be evaluated. The control group consisted of 31 other plant workers from stores and office areas of the plant without previous exposure to ammonia. The mean age of the workers was 38.9 years and duration of exposure was 12.2 years. Weight was the only statistically significant difference in demographics found after comparing height, weight, years worked, % smokers and pack-years smoked. The mean TWA ammonia exposures based on personal sampling over one work shift (average sample collection 8.4 hours) of the exposed and control groups were 9.2 ppm (6.4 mg/cu.m) and 0.3 ppm (0.21 mg/cu.m), respectively.

A questionnaire was administered to obtain information on exposure and work histories and to determine eye, skin and respiratory symptomatology (based on the American Thoracic Society [ATS] questionnaire [Ferris, 1978]). Spirometry (FVC, FEV-1, FEF50 and FEF75) was performed according to ATS criteria at the beginning and end of each work shift on the first workday of the week (day 1) and the last workday of the week (day 2). Differences in reported symptoms and lung function between groups were evaluated using the actual values and with age, height and pack-years smoked as covariates in linear regression analysis. Baseline lung function results were expressed as percent of predicted values calculated from Crapo et al. (1981) for FVC and FEV-1 and from Lapp and Hyatt (1967) for FEF50 and FEF75.

No statistical difference in the prevalence of the reporting symptoms was evident between the exposed and control groups, although workers reported that exposure at the plant had aggravated specific symptoms including coughing, wheezing, nasal complaints, eye irritation, throat discomfort and skin problems. The percentage of exposed workers reporting hay fever or familial history of hay fever was significantly less than controls, suggesting possible self-selection of atopic individuals out of this work force. The atopic status of the worker and control groups was not determined by skin prick tests to common aeroallergens. Furthermore, the workers complained that their symptomatology was exacerbated even though there was no statistical difference between groups. Since the study was cross-sectional in design with a small population, it is possible that selection bias may have occurred.

Baseline lung functions (based on the best spirometry values obtained during the four testing sessions) were similar in the exposed and control groups. No changes in lung function were demonstrated over either work shift (days 1 or 2) or over the workweek in the exposed group

compared with controls. No relationship was demonstrated between chronic ammonia exposure and baseline lung function changes either in terms of the level or duration of exposure, probably due to lack of adequate exposure data for categorizing exposures and thus precluding development of a meaningful index accounting for both level and length of exposure.

Based on the lack of subjective symptomatology and changes in spirometry, this study establishes a free-standing TWA NOAEL of 9.2 ppm (6.4 mg/cu.m). Adjustment for the TWA occupational scenario results in a NOAEL(HEC) of 2.3 mg/cu.m.

Dose and Endpoint for Risk Assessment: The 8 hour-TWA NOAEL of 9.2 ppm (6.4 mg/m^3) was selected based on lack of evidence of decreased pulmonary function or changes in subjective syptomatology in the occupational study (Holness et al. 1989). The 24-hour adjusted NOAEL is 2.3 mg/m^3. This 24-hour NOAEL is the basis of the Agency's inhalation reference concentration (RfC) presented on the Integrated Risk Information System (IRIS) and represents Agency consensus. Since ammonia is a respiratory irritant, the Agency believes that the irritation potential would limit exposure. See USEPA (2005a) for more details on the inhalation RfC and a discussion of other supporting toxicity studies.

Margin of Exposure for Occupational Exposure: For all durations, a MOE of 30 is adequate. An uncertainty factor of 10 is used to allow for the protection of sensitive individuals (intra-species extrapolation). Because it is based on a human epidemiological study, no inter-species safety factor is required. A factor of 3 was used to account for several data base deficiencies including the lack of chronic data, and the lack of reproductive and developmental toxicology studies. This factor is not larger than 3, however, since studies in rats (Schaerdel et al., 1983) have shown no increases in blood ammonia levels at exposures 32 ppm and only minimal increases at 300-1000 ppm, suggesting that no significant distribution is likely to occur at the human equivalent concentration (HEC) level calculated.

B. Dietary Exposure to Monochloroamine

B.1 Acute Reference Dose (RfD)

An acute RfD was not identified because there were no effects attributable to a single dose.

B.2 Chronic Reference Dose (RfD)

Study Selected: Rat Chronic Oral Study (National Toxicology Program 1992)

Executive Summary. The long-term effects of chloraminated water were examined in F344/N rats and B6C3F1 mice (NTP, 1992). Groups of rats (70/sex/dose) and mice (70/sex/dose) were administered chloraminated drinking water at 0 (controls), 50, 100 or 200 ppm for 103-104 weeks. Based on body weight and water consumption data provided in the study, the intake of

chloramine was 0, 2.6, 4.8 and 8.7 mg/kg-day for male rats; 0, 3.4, 5.3 and 9.5 mg/kg-day for female rats. Consumption of chloramine in mice was 0, 5.0, 8.9 and 15.9 mg/kg-day for males; and 0, 4.9, 9.0 and 17.2 mg/kg-day for females. Interim sacrifices (10/sex/dose) were conducted at weeks 14 and 66. At these times, a complete hematologic examination and necropsy were performed in all sacrificed animals. In addition, histopathologic examination was conducted in all control and high-dose animals. At the completion of the study, a complete histopathologic evaluation was performed in all animals. A dose-related decrease in water consumption was evident in rats throughout the study; food consumption was not affected by treatment. Mean body weights of high-dose male and female rats were lower than their respective controls. However, mean body weights were within 10% of controls until week 97 for females and week 101 for males. Decreases ($p<0.05$) in liver and kidney weight in the high-dose males and increases ($p<0.05$) in the brain- and kidney-to-body weight ratios in the high- dose rats (both sexes) were related to lower body weights in these groups and were not considered toxicologically significant. Results from pathologic evaluation at weeks 14 and 66 were unremarkable. The authors found no clinical changes attributable to consumption of chloraminated water. There were no non-neoplastic lesions after the 2-year treatment with chloraminated water. A NOAEL for rats of 200 ppm chloramine, or 9.5 mg chloramine/kg/day, can be defined in this study.

In treated mice, water consumption throughout the study was also decreased in a dose-related manner. Food consumption was slightly lower in high-dose females compared with controls. Body weights of treated male and female mice were lower than in controls; the effect was dose-related. On the average, body weights of high-dose males were 10-22% lower than controls after week 37; those of high-dose females were 10-35% lower than controls after week 8. Mice exhibited no adverse clinical signs attributed to treatment with chloramine. Survival rates between treated and control mice were not significantly different. Interim evaluations revealed no biologically significant differences in organ weights or in relative organ weights. There were occasional statistically significant differences, such as decreases in liver weights and increases in brain- and kidney-to-body weight ratios in high-dose male and female mice, but these were attributed to the lower body weights and were not considered toxicologically significant. Results from hematology tests, and gross or microscopic examination of tissues and organs were unremarkable. The 2-year evaluation revealed no non-neoplastic lesions attributable to chloramine treatment. The concentration of 200 ppm chloramine, or 17.2 mg chloramine/kg/day is considered a NOAEL for mice in this study.

Dose and Endpoint for Risk Assessment: The NOAEL of 9.5 mg/kg/day (200 ppm) was selected based on no observable adverse effects in the rat chronic oral study (NTP 1992). This NOAEL is the basis of the Agency's oral reference dose (RfD) presented on the Integrated Risk Information System (IRIS) and represents Agency consensus. Although a higher NOAEL in the study of 17.2 mg/kg-day is found for mice, rats may be the more sensitive species since doses between 9.5 and 17.2 mg/kg-day were not tested in rats. Significant decreased weight gain in subchronic rat studies, such as Daniel et al. (1990), at 200 ppm was considered a consequence of decreased water consumption associated with taste aversion.

Uncertainty factors: 100 (10x interspecies extrapolation, 10x intraspecies variation, 1x FQPA safety factor). The FQPA safety factor is reduced to 1X for monochloramine because data from

existing reproductive and developmental studies across chemical class (monochloramine and chlorine) provide sufficient confidence that the reproductive and developmental issues have been addressed. Although the studies with chlorine are marginal in quality, they do give an indication that adverse effects from monochloramine are not likely to occur (see Section 2.3).

Comments about Study/Endpoint Uncertainty Factor: This study represents the best available data to assess chronic toxicity.

$$\textbf{Chronic RfD} = \frac{\text{9.5 mg/kg/day (NOAEL)}}{\text{100 (UF)}} = \textbf{0.1 mg/kg/day}$$

C. Classification of Carcinogenic Potential

Ammonia: There is no evidence that ammonia causes cancer. Ammonia has not been classified for carcinogenic effects by EPA, the Department of Health and Human Services (DHHS), or the International Agency for Research on Cancer (IARC) (ATSDR 2004).

Monochloramine: Monochloramine is not classifiable as to human carcinogenicity (Group D) based on inadequate human data and equivocal evidence of carcinogenicity from animal bioassays. A two-year bioassay showed marginal increase in mononuclear cell leukemia in female F344/N rats. No evidence of carcinogenic activity was reported in male rats or in male or female B6C3F1 mice. Genotoxcity studies, both in vitro and in vivo, gave negative results (USEPA 2005b).

4.0 FQPA CONSIDERATIONS

4.1 Special Sensitivity to Infants and Children

Ammonia: The Agency acknowledges that there is a lack of adequate reproductive and developmental toxicology studies for ammonia in the IRIS record (USEPA 2005a). However, based on the proposed use pattern, BCMW/BUSAN 1215 containing dilute solutions of ammonia is mixed with sodium hypochlorite (12.5%) to form monochloramine in pulp/paper. Because there is no concern for potential dietary exposure to ammonia for this proposed use pattern, it is not necessary to consider the FQPA safety factor for ammonia. However, the Agency believes the FQPA factor should be considered for the potential dietary exposures to monochloramine.

Monochloramine: As noted in the USEPA (2005b) IRIS record, the developmental and reproductive toxicity of monochloramine has been examined in rats, but with suboptimal studies. These studies are summarized below. However, due to the chemical relationship

between monochloramine and chlorine (U.S. EPA, 1992), reproductive and developmental studies for chlorine (Druckrey, 1968; McKinney et al., 1976; Chernoff et al., 1979; Staples et al., 1979; Meier et al., 1985) may be used to satisfy these data gaps for monochloramine. The available studies do not indicate concerns for increased sensitivity of the fetus or offspring. Thus, the Agency believes it is appropriate to reduce the FQPA factor to 1X for monochloramine.

Tale 2
Summary of Toxicological Dose and Endpoints for Ammonia [1]

Exposure Scenario	Dose Used in Risk Assessment, UF	[illegible]	Study and Toxicological Effects
Dermal (all durations) (Occupational)	Labels will specify the use of gloves, full body clothing and eye protection.		
Inhalation (all durations) (Occupational)	NOAEL= 6.3 mg/m^3 (9.2 ppm) 8-hr TWA NOAEL(HEC)= 2.3 mg/m^3 (24 hour concentration)	LOC for MOE = 30 (Occupational)	Occupational Study (Holness et al. 1989) LOAEL= none See IRIS record (USEPA 2005a) for more detailed discussion.

[1] *UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, LOC=level of concern , MOE = margin of exposure, HEC= human equivalent concentration*

New Active Ingredient Notice of Receipt Information
Dennis Edwards to: Tracy Lantz 01/05/2011 07:56 AM
Cc: Velma Noble

Hi Tracy,

Below is the information on the Nalco ammonia application filings. Three products containing two new active ingredients. All you need to do is get a docket number and sent the docket number and the information below to Caroline by Thursday. (You will need the signed docket form.)

1706
1) File symbol: ~~1707~~ - EUN Nalco 60620
Applicant: Nalco Company, 1601 West Diehl Road, Naperville, IL 60563
Active Ingredient: Ammonium sulfate @ 20%
Proposed Use: Pulp and papermill water systems
Contact: Tracy Lantz, 703-308-6415, Lantz.Tracy@EPA.gov

2) File Symbol 1706-EGO Nalco 60615
Applicant: Nalco Company, 1601 West Diehl Road, Naperville, IL 60563
Active Ingredient: Urea @ 15 %
Proposed Use: Pulp and papermill water systems
Contact: Tracy Lantz, 703-308-6415, Lantz.Tracy@EPA.gov

revised data matrix

data: Group A + Group B Chemistry RASSB

3) File Symbol 1706-EUR Nalco 60630
Applicant: Nalco Company, 1601 West Diehl Road, Naperville, IL 60563
Active Ingredient: Urea @ 30 %
Proposed Use: Pulp and papermill water systems
Contact: Tracy Lantz, 703-308-6415, Lantz.Tracy@EPA.gov

revised data matrix

Dennis

Data recd 1/12/11
Data sent to review 1/12/11
NOR will publish on 2/2/11

Notice of Receipt: all info sent to Caroline on 1/6/11

Dennis Edwards, Chief
Regulatory Management Branch 1
Antimicrobials Division
703-308-8087

1706 - EUN is similar to:
1448-432
1448-433

Urea:
look @ RED

Talk to Teresa -
does she have data??
prod. Chemistry
~~accepted~~ acutes for 1706-EUN
Put into review
Spoking w/ PSB + RASSB
Sent additional study MRID 483512-01 & Rainbow Trout to review on 1/19/11 w/ DP385698

1/13/11 called Juli Mann regarding rejected study for rainbow trout.
Faxed rejection letter - took corrected study (vol. 1) to Teresa for return to me 11/18/11

Re: [redacted]

[redacted]

Dennis Edwards to: Philip Ross 03/02/2011 05:50 PM
Cc: Chris Kaczmarek, Joan Harrigan-Farrelly, Tracy Lantz

Phil

[redacted]

Dennis

Dennis Edwards, Chief
Regulatory Management Branch 1
Antimicrobials Division
703-308-8087

Philip Ross Attorney Client Communication Attorney Work P... 03/02/2011 12:55:24 PM

From: Philip Ross/DC/USEPA/US
To: Dennis Edwards/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA
Cc: Chris Kaczmarek/DC/USEPA/US@EPA
Date: 03/02/2011 12:55 PM
Subject: [redacted]

Attorney Client Communication
Attorney Work Product
Deliberative
Privileged and Confidential
Do Not Release

Internal deliberative
Privileged attorney-client communication

[redacted]

Thanks.

Phil

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

Internal deliberative

Privileged attorney-client communication

appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This information collection is being conducted by EPA's Office of Air and Radiation (OAR) to assist the EPA Administrator, as required by sections 111(b), 112(d), and 112(f)(6) of the Clean Air Act (CAA), as amended, to reevaluate emission standards for this source category. The non-confidential information from this information collection request (ICR) would also be made available to the public.

The proposed ICR has four components. To obtain the information necessary to identify and categorize all units potentially affected by any future revision to a standard, the first component of this ICR will solicit information from all potentially affected units at all 152 refineries in the format of an electronic survey under authority of section 114 of the CAA. This survey will include questions about the facility and individual emissions sources, and it will ask the owners/operators to submit cost data and provide copies of recent emissions test reports and continuous emission monitoring system (CEMS)/ continuous monitoring system (CMS) data. The second component will ask the owners/operators to develop and provide an emissions inventory. The third component will ask the owners/ operators to conduct sampling and analysis of the feed to the distillation columns at their refinery over a specific time period. The first three components will be submitted to all facilities listed in the *Energy Information Administration's Refinery Capacity Report 2009*. The fourth component will consist of requiring emissions testing, again pursuant to the authority of section 114 of the CAA.

EPA is issuing a single collection of information for sources covered under 40 CFR part 63, subparts CC and UUU and 40 CFR part 60, subpart J so that EPA can, at one time, assess whether additional control strategies are necessary and, if so, which are the most effective for hazardous air pollutants (HAP), regulated under CAA section 112, and criteria air pollutants (such as particulate matter, sulfur dioxide, and nitrogen oxide), regulated under CAA section 111. The data would also allow EPA to evaluate compliance options for startup and shutdown periods and consider ways to consolidate monitoring, reporting and recordkeeping requirements for the different rules under review. The data may also help EPA conduct reviews of other rules specific to petroleum refineries, including Standards of Performance for Equipment Leaks of VOC in Petroleum Refineries (40 CFR part 60, subpart GGG), Standards of Performance for VOC Emissions from Petroleum Refinery Wastewater Systems (40 CFR part 60, subpart QQQ), and the National Emission Standard for Benzene Waste Operations (40 CFR part 61, subpart FF).

The data collected will be used to update and augment facility and emissions source information already available to the Agency, develop new estimates of the population of affected units, and identify the control measures and alternative emission limits being used for compliance with the existing rules that are under review. This information, along with existing emission limits, will be used to establish the baseline emissions and control levels for purposes of the regulatory reviews. The emissions test data (test reports, CEMS data, and CMS data) collected will be used to assess the effectiveness of existing control measures, examine variability in emissions, evaluate the stringency of existing emission limits, identify the most effective control measures considered for purposes of reducing residual risk, and provide a basis for estimating nationwide emissions from emissions sources for which EPA has little information. Emissions data will also be used, along with process and emissions unit details, to consider options for best demonstrated technology under the NSPS review, to consider subcategories for further regulation, and to estimate the environmental and cost impacts associated with any regulatory options considered.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 256 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and use technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Respondents affected by this action are owners/operators of petroleum refineries, all of which are expected to have the potential to be subject to one of the regulatory standards being reviewed or developed by EPA. Petroleum refineries are facilities engaged in refining and producing products made from crude oil or unfinished petroleum derivatives.

Estimated Number of Respondents: 152.

Frequency of response: Once.

Estimated total annual burden hours: 69,342 hours.

Estimated total annual burden costs: $30,924,069, which includes $912 in O&M costs.

Dated: January 26, 2011.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2011-2273 Filed 2-1-11; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0004; FRL-8862-1]

Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any previously registered pesticide products. Pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before March 4, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the file symbol(s) for the product(s) of interest as listed in Unit II, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S.

Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to the docket ID number and the file symbol(s) for the product(s) of interest as listed in Unit II. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulotions.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although, listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulotions.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: The Regulatory Action Leader listed in the table in this unit:

Regulatory action leader	Telephone number and e-mail address	Mailing address	File symbol
Susanne Cerrelli	(703) 308–8077 *cerrelli.susanne@epa.gov*	Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania, Ave., NW., Washington, DC 20460–0001.	7005t–RNT, 7005f–RNI.
Anna Gross	(703) 305–5614 *gross.anna@epa.gov*	Do	84059–RG, 84059–RU.
Chris Pfeifer	(703) 308–0031 *pfeifer.chris@epa.gov*	Do	34704–RNLL, 34704–RNLA, 34704–RNLT.
Jeannine Kausch	(703) 347–8920 *kausch.jeannine@epa.gov*	Do	84059–RA, 85004–I, 85004–O.
Abigail Downs	(703) 305–5259 *downs.abigail@epa.gov*	Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania, Ave., NW., Washington, DC 20460–0001.	707–GEN, 707–GRO.
Jacqueline Campbell-McFarlane	(703) 308–6416 *campbell-mcfarlane.jacqueline@epa.gov*	Do	5383–RUE, 5383–RUN.
Tracy Lantz	(703) 308–6415 *Lantz.tracy@epa.gov*	Do	1706–EUN, 1706–EUR, 1706–EGO.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI

must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, Federal Register date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any previously registered pesticide products. Pursuant to the provisions of section 3(c)(4) of FIFRA, EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

1. *File Symbol:* 707–GEN. *Docket Number:* EPA–HQ–OPP–2010–1037. *Applicant:* Rohm and Hass Company, 100 Independence Mall West, Philadelphia, PA 19106. *Product nome:* Bioban MB 100 Technical. *Active ingredient:* microbiocide and 2-methyl-1, 2-benzisothiazolin-3-one at 98.90%. *Proposed classification/Use:* Technical. (Abigail Downs)

2. *File Symbol:* 707–GRO. *Docket Number:* EPA–HQ–OPP–2010–1037. *Applicont:* Rohm and Hass Company, 100 Independence Mall West, Philadelphia, PA 19106. *Product name:* Bioban MB 25 Antimicrobial. *Active ingredient:* Microbiocide and 2-methyl-1, 2-benzisothiazolin-3-one at 25%. *Proposed classificotion/Use:* For use in formulation of emulsion products, paints, building materials, adhesives and sealants, ink, textiles, paper coating, functional chemicals, household and I&I, oil process water and recovery system, metalworking fluids. (Abigail Downs)

3. *File Symbol:* 1706–EUN. *Docket Number:* EPA–HQ–OPP–2011–0019. *Applicant:* Nalco Company, 1601 West Diehl Road, Naperville, IL 60563. *Product nome:* Nalco 60620. *Active ingredient:* Antimicrobial and Ammonium Sulfate at 20%. *Proposed classification/Use:* Pulp and paper mill water systems. (Tracy Lantz)

4. *File Symbol:* 1706–EUR. *Docket Number:* EPA–HQ–OPP–2011–0020. *Applicont:* Nalco Company, 1601 West Diehl Road, Naperville, IL 60563. *Product name:* Nalco 60630. *Active ingredient:* Antimicrobial and Urea at 30%. *Proposed classificotion/Use:* Pulp and paper mill water systems. (Tracy Lantz)

5. *File Symbol:* 1706–EGO. *Docket Number:* EPA–HQ–OPP–2011–0020. *Applicont:* Nalco Company, 1601 West Diehl Road, Naperville, IL 60563. *Product name:* Nalco 60615. *Active ingredient:* Antimicrobial and Urea at 15%. *Proposed classificotion/Use:* Pulp and paper mill water systems. (Tracy Lantz)

6. *File Symbol:* 5383–RUE. *Docket Number:* EPA–HQ–OPP–2009–1000. *Applicant:* Troy Chemical, Inc., 8 Vreeland Rd., P.O. Box 955, Florham Park, NJ 07932–4200. *Product name:* TROYSAN V662. *Active ingredient:* Antimicrobial and Terbutryn at 48%. *Proposed classificotion/Use:* Materials preservation of coatings, stuccos, roof coatings, joint cements, and sealants. (Jacqueline Campbell-McFarlane)

7. *File Symbol:* 5383–RUN. *Docket Number:* EPA–HQ–OPP–2009–1000. *Applicant:* Troy Chemical, Inc., 8 Vreeland Rd., P.O. Box 955, Florham Park, NJ 07932–4200. *Product name:* POLYPHASE ® 710 S. *Active ingredient:* Antimicrobial and Terbutryn at 8%. *Proposed classification/Use:* Materials preservation of joint cements, coatings, sealants, stuccos, and plastics. (Jacqueline Campbell-McFarlane)

8. *File Symbol:* 34704–RNLL. *Docket number:* EPA–HQ–OPP–2011–0009. *Applicont:* Loveland Products, Inc., c/o Pyxis Consulting, Inc., 4110 136th St., NW., Gig Harbor, WA 98332. *Product name:* LPI 6194 Concentrate Seed Treatment. *Active ingredient:* Plant growth regulator, Salicylic Acid, at 0.04%. *Proposed classificotion/Use:* Biochemical pesticide/plant growth regulator intended for seed treatment. (Chris Pfeifer)

9. *File Symbol:* 34704–RNLA. *Docket number:* EPA–HQ–OPP–2011–0009. *Applicant:* Loveland Products, Inc., c/o Pyxis Consulting, Inc., 4110 136th St., NW., Gig Harbor, WA 98332. *Product name:* LPI 6194 RTU Seed Treatment. *Active ingredient:* Plant growth regulator, Salicylic Acid, at 0.0067%. *Proposed classification/Use:* Biochemical pesticide/plant growth regulator intended for seed treatment. (Chris Pfeifer)

10. *File Symbol:* 34704–RNLT. *Docket number:* EPA–HQ–OPP–2011–0009. *Applicant:* Loveland Products, Inc., c/o Pyxis Consulting, Inc., 4110 136th St., NW., Gig Harbor, WA 98332. *Product nome:* Salicylic Acid Technical. *Active ingredient:* Plant growth regulator, Salicylic Acid, at 98.7%. *Proposed clossification/Use:* Biochemical pesticide/manufacturing use product containing a plant growth regulator intended for incorporation into end use products for seed treatment. (Chris Pfeifer)

11. *File Symbol:* 70051–RNT. *Docket number:* EPA–HQ–OPP–2010–0944. *Applicant:* Certis U.S.A., L.L.C., 9145 Guilford Road, Suite 175, Columbia, MD 21046. *Product name:* CX–9032. *Active ingredient:* Fungicide and *Bacillus subtilis var. amyloliquefaciens stroin D747* at 98.35%. *Proposed clossificotion/Use:* Fungicide on vegetable, melons, tree fruit and nuts, strawberry, berries, grapes, tropical fruits, herbs, coffee, mint, hops, tobacco, nurseries, greenhouses, shade house, ornamental plants and turf. (Susanne Cerrelli)

12. *File Symbol:* 70051–RNI. *Docket number:* EPA–HQ–OPP–2010–0944. *Applicont:* Certis U.S.A., L.L.C., 9145 Guilford Road, Suite 175, Columbia, MD 21046. *Product name:* CX–9030. *Active ingredient:* Fungicide and *Bocillus subtilis var. omyloliquefaciens strain D747* at 25.0%. *Proposed clossification/Use:* Fungicide on vegetable, melons, tree fruit and nuts, strawberry, berries, grapes, tropical fruits, herbs, coffee, mint, hops, tobacco, nurseries, greenhouses, shade house, ornamental plants and turf. (Susanne Cerrelli)

13. *File Symbol:* 84059–RA. *Docket Number:* EPA–HQ–OPP–2010–0058. *Applicont:* Marrone Bio Innovations, Inc., 2121 Second St., Suite B–107, Davis, CA 95618. *Product Nome:* MBI–203 SC. *Active Ingredient:* Insecticide and *Chromobocterium subtsugoe* strain PRAA4–1^T at 86.50%. *Proposed classification/Use:* For control of foliar-feeding pests, such as caterpillars, foliage-feeding coleopteran, aphids, whiteflies, and plant-sucking mites, on ornamental plants, turf, and various edible crops. Note: In the Federal Register of March 10, 2010 (75 FR 11175) (FRL–8811–6), EPA announced

receipt of two other applications to register pesticide products containing this new active ingredient. (J. Kausch)

14. *File Symbol:* 84059–RG. *Docket Number:* EPA–HQ–OPP–2011–0010. *Applicant:* Marrone Bio Innovations, 2121 Second Street, Suite B–107, Davis, CA 95618. *Product name:* MBI–206 TGAI. *Active ingredient:* Insecticide and *Burkholderia sp.* strain A396 at 100%. *Proposed classification/Use:* Ornamental plants, turf and edible crops. (Anna Gross)

15. *File Symbol:* 84059–RU. *Docket Number:* EPA–HQ–OPP–2011–0010. *Applicant:* Marrone Bio Innovations, 2121 Second Street, Suite B–107, Davis, CA 95618. *Product name:* MBI–206 EP. *Active ingredient:* Insecticide and *Burkholderio sp.* strain A396 at 94.46%. *Proposed classification/Use:* Ornamental plants, turf and edible crops. (Anna Gross)

16. *File Symbol:* 85004–I. *Docket Number:* EPA–HQ–OPP–2010–0808. *Applicant:* MacIntosh and Associates, Inc., 1203 Hartford Ave., Saint Paul, MN 55116–1622 (on behalf of Pasteuria Bioscience, Inc., 12085 Research Dr., Suite 185, Alachua, FL 32615] *Product Name: Posteuria reniformis*—Liquid Formulation. *Active Ingredient:* Nematicide and *Pasteurio reniformis*—Pr3 [SD–5834] at 0.0033%. *Proposed Classification/Use:* For control of reniform nematode (*Rotylenchulus reniformis)* on various food and nonfood crops. Note: In the Federal Register of November 24, 2010 (75 FR 71697) (FRL–8837–3), EPA announced receipt of two other applications to register pesticide products containing this new active ingredient. [J. Kausch)

17. *File Symbol:* 85004–O. *Docket Number:* EPA–HQ–OPP–2010–0806. *Applicant:* MacIntosh and Associates, Inc., 1203 Hartford Ave., Saint Paul, MN 55116–1622 [on behalf of Pasteuria Bioscience, Inc., 12085 Research Dr., Suite 185, Alachua, FL 32615.) *Product Nome: Pasteuria nishizawoe*—Liquid Formulation. *Active Ingredient:* Nematicide and *Pasteuria nishizawae*—Pn1 [SD–5833] at 0.0033%. *Proposed Classificotion/Use:* For control of soybean cyst nematode (*Heterodera glycines)* on soybean. Note: In the Federal Register of November 24, 2010 (75 FR 71697) (FRL–8837–3), EPA announced receipt of two other applications to register pesticide products containing this new active ingredient. (J. Kausch)

List of Subjects

Environmental protection, Agricultural Commodities, Pesticides and pest.

Dated: January 20, 2011.

Keith A. Matthews,

Acting Director, Biopesticides Pollution Prevention Division, Office of Pesticide Progroms.

[FR Doc. 2011–2156 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0548; FRL–8863–6]

Petition for a Ban on Triclosan; Notice of Availability; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; extension of comment period.

SUMMARY: EPA issued a notice in the Federal Register of December 8, 2010 concerning the availability of a petition submitted by Beyond Pesticides and Food & Water Watch to the Environmental Protection Agency for review and public comment. The petition asks EPA to use its authority under various statutes to regulate triclosan. In a letter to the EPA dated January 22, 2011, Beyond Pesticides and Food & Water Watch requested a 60 day extension to the comment period. In response to this request, this document extends the comment period for 60 days, from February 7, 2011 to April 8, 2011.

OATES: Comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0548, must be received on or before April 8, 2011.

ADDRESSES: Follow the detailed instructions as provided under **AODRESSES** in the Federal Register document of December 8, 2010.

FOR FURTHER INFORMATION CONTACT: Timothy F. McMahon, Antimicrobials Division [7510P], Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6342; e-mail address: *mcmahon.tim@epa.gov.*

SUPPLEMENTARY INFORMATION: This document extends the public comment period established in the Federal Register of December 8, 2010 (75 FR 764613) (FRL–8852–8). In that document, the Agency made available for review and public comment a petition submitted by Beyond Pesticides and Food & Water Watch [hereafter referred to as "the petitioners") to the Environmental Protection Agency (hereafter referred to as "EPA" or "the Agency"), asking EPA to use its authority under various statutes to regulate triclosan. Triclosan is an antimicrobial substance used in pesticide products, hand sanitizers, toothpaste, and other consumer products. The petitioners claim that the "pervasive and widespread use" of triclosan poses significant risks to human health and the environment. In addition, the petitioners claim that the "agency failed to address the impacts posed by triclosan's degradation products on human health and the environment, failed to conduct separate assessments for triclosan residues in contaminated drinking water and food, and is complacent in seriously addressing concerns related to antibacterial resistance and endocrine disruption." Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), the petitioners ask EPA to act to cancel and suspend the registration of pesticides containing triclosan. Under the Clean Water Act (CWA), the petitioners request that the Administrator impose technology-based effluent limitations, health-based toxic pollutant water quality pretreatment requirements, and biosolids regulation for triclosan. Under the Safe Drinking Water Act (SDWA), the petitioners request that the Administrator conduct a comprehensive assessment of the appropriateness of regulating triclosan under SDWA. Under the Endangered Species Act (ESA), the petitioners request that the Administrator comply fully with ESA, including consultation and biological assessment requirements. In a letter submitted to the Agency dated January 22, 2011, Beyond Pesticides and Food & Water Watch requested a 60 day extension to the comment period. EPA is hereby extending the comment period, which was set to end on February 7, 2011, to April 8, 2011.

To submit comments, or access the docket, please follow the detailed instructions as provided under **ADDRESSES** in the December 8, 2010 Federal Register document. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

List of Subjects

Environmental protection, Antimicrobial, Pesticides and pest, Triclosan, Endocrine.

Dated: January 26, 2011.

Joan Harrigan Farrelly,

Director, Antimicrobiols Division, Office of Pesticide Progroms.

[FR Doc. 2011–2267 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

Fw: Status of Jan 7 batch-- Notice of Receipt of Applications batch will publish tomorrow 2-2-11

Caroline Klos to: Joan Harrigan-Farrelly, Jennifer Mclain, Dennis Edwards 02/01/201 t 02:36 PM

Cc: Tracy Lantz

Nalco NOR will publish tomorrow.

----- Forwarded by Caroline Klos/DC/USEPA/US on 02/0 t/20 t1 02:35 PM -----

From:	Susanne Cerrelli/DC/USEPA/US
To:	Caroline Klos/DC/USEPA/US@EPA, Abigail Downs/DC/USEPA/US@EPA, Tracy Lantz/DC/USEPA/US@EPA, Jeannine Kausch/DC/USEPA/US@EPA, Jacqueline Campbell-McFarlane/DC/USEPA/US@EPA, Chris Pfeifer/DC/USEPA/US@EPA, Anna Gross/DC/USEPA/US@EPA
Cc:	Andrew Bryceland/DC/USEPA/US@EPA, Michael Mcdavit/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA
Date:	02/0 t/2011 02:33 PM
Subject:	Re: Status of Jan 7 batch-- Notice of Receipt of Applications batch will publish tomorrow 2-2-t1

FYI-

Thanks for your rapid response! Below is the link to our FR Notice that is to publish tomorrow. See link at the Office of Federal register below:

http://www.ofr.gov/OFRUpload/OFRData/2011-02156_PI.pdf

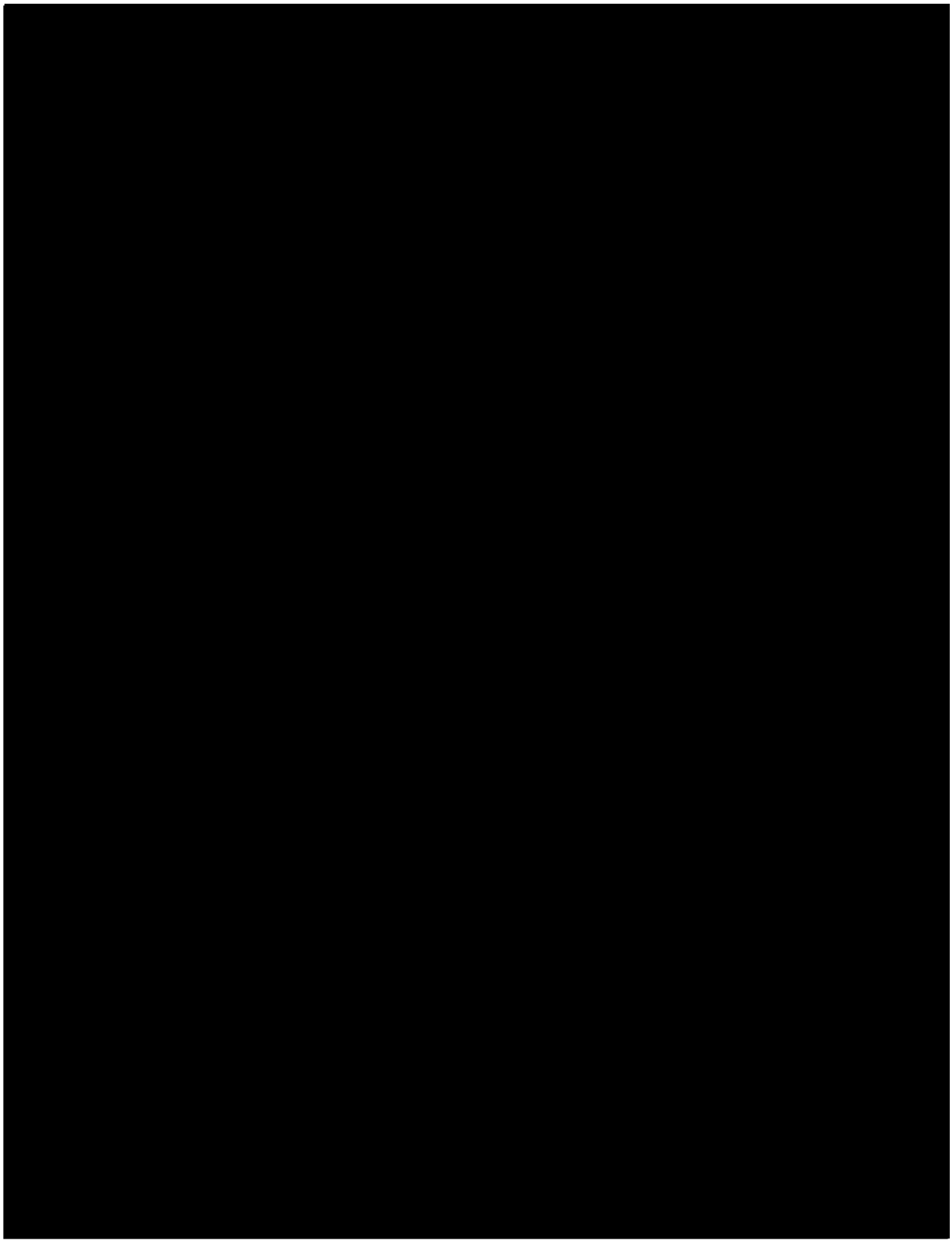
Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

Ammonia Timeline



Internal deliberative

[redacted]

Internal deliberative

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
__ Reregistration

(under FIFRA, as amended)

EPA Reg Number:	Date of Issuance
1448-432	MAR - 6 2007

Term of Issuance: **Conditional**

Name of Pesticide Product: **BCMW**

Name and Address of Registrant (include ZIP Code):

Buckman Laboratories, Inc.
1256 N. McLean Blv.
Memphis, TN 38108

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No. 1448-432

Signature of Approving Official:

Velma Noble
Product Manager Team-31
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: MAR - 6 2007

EPA Form 8570-6

Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Velma Noble
Product Manager 31
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosure:

BUSAN 1215

BUSAN is a registered trademark.

A microbiocide for controlling algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products.

ACTIVE INGREDIENT(S):

Ammonia (total)	7.59%
INERT INGREDIENTS	92.41%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
If Swallowed	- Call poison control center or doctor immediately for treatment advice. - Have person sip a glass of water, if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If Inhaled	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-276-0330 or 1-800-BUCKMAN for emergency medical treatment information.	

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PULP AND PAPER MILLS: BUSAN 1215 can be used as a microbiocide in the manufacture of paper and paperboard that contacts food.

This product is applied in conjunction with sodium hypochlorite (12.5% ai) to form monochloramine, a slower acting less aggressive oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.5:1.0 product to 1.0 of ammonia to oxidant, and this ratio is obtained by combining 0.6 fluid ounces of BUSAN 1215 to 1 fluid ounce of sodium hypochlorite (12.5 ai). To ensure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Buckman representative. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment mix 0.6 fluid ounces of BUSAN 1215 to 1 fluid ounce of sodium hypochlorite (12.5% a.i.). Apply solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 5 ppm measured) as total chlorine in the process water or stock being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

For continuous treatment mix 0.6 fluid ounces of BUSAN 1215 to 1 fluid ounce of sodium hypochlorite (12.5% a.i.). Apply solution at a rate to obtain at least 1 ppm in excess of system oxidant demand (maximum of 5 ppm) measured as total chlorine in the process water or stock being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

If chloramine is detected in the effluent, it can be neutralized by the addition of sodium meta bisulfite until the chloramine is no longer detected.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources.

CONTAINER DISPOSAL

PLASTIC: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

METAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Manufactured by

Buckman Laboratories, Inc.

1256 North McLean Blvd.

Memphis, Tennessee 38108, USA

(901) 276-0330 or 1-800-BUCKMAN

EPA Est. No.	1448-TN-1
EPA Reg. No.	1448-
Product Weight	9.59 lbs/gal 1.15kg/l

Net contents are marked on the container.

HMIS / NPCA Ratings

Health 1 Flammability 1 Reactivity 0

Last Revision 2/21/2007

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAR - 6 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1448-433

U. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Number: 8622-64

Date of Issuance: May 5, 2003

Term of Issuance: Conditional

Name of Pesticide Product: Fuzzicide Solution

NOTICE OF PESTICIDE:

x Registration

__ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Ameribrom, Inc.
2115 Linwood Ave.
Ft. Lee, NJ 07024

Note: Changes in label wording in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to the use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C) provided you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Change EPA File symbol 8622-AU to EPA Registration Number 8622-64.

3. Under Spills, fix typo after pesticide disposal by replacing comma with a period.

4. Submit one copy of the final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Thomas D Luminella

for Robert S. Brennis
Product Manager 32

Date: MAY - 5 2003

EPA Form 8570-6

FUZZICIDE® SOLUTION
(AMMONIUM BROMIDE SOLUTION)

A BACTERICIDE, SLIMICIDE AND ALGICIDE FOR TREATING
RECIRCULATING COOLING WATER SYSTEMS AND PULP & PAPER MILLS

Active Ingredient: Ammonium bromide	35.0%
Other Ingredients:	65.0%
Total.....	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If swallowed	• Call poison control center, or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

USE WITH ADEQUATE VENTILATION
WASH THOROUGHLY AFTER HANDLING

See side panels for additional precautionary statements.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAY - 5 2003

Under the Federal Insecticide, [illegible] Act
for the registration
Registration No.
8622-264

EPA Reg. No. 8622-AU
EPA Est No.

NET CONTENTS: _____ LBS.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAY - 5 2003
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No. 8622-64

PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION

CAUSES MODERATE EYE IRRITATION

Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms. Do not contaminate water by cleaning of equipment or disposal of waste. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DIRECTIONS FOR USE

FUZZICIDE® SOLUTION is to be used only in conjunction with: 1) an oxidant such as sodium hypochlorite (typically 12.5%) to produce FUZZICIDE® biocide; and 2) the FUZZICIDE® feeder/delivery system (described below).
FUZZICIDE® SOLUTION and the oxidant are mixed in a specially designed reactor which produces the biocide on site. The Fuzzicide feeding system controller ensures the automatic production of the dilute biocide solution and controls the optimization of the biocide production process. The design of treatment, installation, calibration and operation of the feeding system in all plants should be conducted only by authorized and trained personnel.

Use of this product for any other purposes or contrary to the instructions below, or without the supervision of authorized trained personnel is prohibited.
The biocide produced by the feeder is immediately added to the process waters for which treatment is required. The biocide may be added to any point of uniform mixing. Addition may be continuous or intermittent depending on the severity of the contamination when treatment starts, and on other system operation parameters.

Note: Do not use other feeding modes to mix FUZZICIDE® SOLUTION and the oxidant, or mix FUZZICIDE® SOLUTION with other additives so as to avoid decomposition of the biocide. Non-authorized personnel are prohibited from operating or otherwise handling the feeding system or its chemical ingredients.

RECIRCULATING COOLING SYSTEMS

Used effectively at dosages recommended to achieve exposure to 0.3-5.0 parts per million (ppm) of residual biocide expressed as total chlorine, or as needed to maintain control of algal, bacterial, and fungal slimes in industrial cooling towers, evaporative condensers, heat exchange water towers, influent systems such as flow through filters, industrial water scrubbing systems, brewery pasteurizers, sewage systems (septic tanks, leach fields, tank lines, serers, lagaoons, and sewage effulent water) industrial air-washing systems equipped with a mist eliminator.

Dosage Rates

Initial dose: When noticeably fouled, add sufficient biocide produced by the reactor to achieve a measured concentration of 0.3 - 5.0 ppm residual biocide, expressed as total chlorine. The recommended dosage is typically achieved by mixing 0.54 gallons of Sodium Hypochlorite (12.5%) with 0.22 gallons of FUZZICIDE® SOLUTION in the reactor.

Subsequent Dose: Once microbial control is evident, add sufficient biocide produced by the reactor to maintain the measured residual biocide concentration at 0.3 - 5.0 ppm in process waters, expressed as total chlorine. Continue as in initial dose.

PULP AND PAPER MILLS (and associated cooling water systems and waste water treatment systems)

Used for the control of algal, bacterial and fungal slimes, in pulp and paper mill fresh and sea water influent systems, ~~cooling water systems, wastewater treatment systems,~~ pulp, paper and paper board mills systems, nonpotable water systems, starch slurries, and other process water. Apply biocide as directed.

Dosage Rates

Initial dose: When noticeably fouled, add sufficient biocide produced by the reactor to achieve a measured concentration of 0.3 -10.0 ppm residual biocide, expressed as total chlorine. The recommended dosage is typically achieved by mixing 0.54 gallons of Sodium Hypochlorite (12.5%) with 0.22 gallons of FUZZICIDE® SOLUTION in the reactor. Do not exceed 0.14 gallons of FUZZICIDE® SOLUTION per 2205 pounds of dry weight fiber in paper and paperboard components that contact food.

Subsequent Dose: Once microbial control is evident, add sufficient biocide produced by the reactor to maintain the measured residual biocide concentration at 0.3 -10.0 ppm in process waters, expressed as total chlorine.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE

Store in a cool, dry, well-ventilated area, in well-closed original containers, away from energy sources, acids, alkaline, and heavy metal salts.

ACCEPTED
COMMENTS
Letter Dated:
MAY - 5 2003

...insecticide,
...cide Act as
...ide.

8622-269

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control agent or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Waste resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility. Completely empty container into application equipment. Then dispose of empty container in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SPILLS

When handling or dealing with spills, use impact-resistant goggles with side shields or face shield; body-covering clothes, including impervious rubber or plastic gloves and boots; use approved respirator. Absorb on sand or vermiculite and place in closed container and dispose as described for pesticide disposal. If containers are contaminated or decomposing, do not reseal; isolate unsealed container in the open or a well-ventilated area; flood with large volumes of water if necessary.

DO NOT SMOKE, DRINK, OR EAT WHEN HANDLING

DO NOT SHIP WITH FOOD, FEEDS, DRUGS, OR CLOTHING.

KEEP CONTAINER TIGHTLY CLOSED WHEN NOT IN USE

WARRANTY

Seller warrants that this product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with label directions under normal conditions of use, but neither this warranty nor any other warranty of MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such use.

Manufactured for:
Ameribrom, Inc.
2115 Linwood Avenue
Fort Lee, NJ 07024-5004
Tel: (201) 242-6560
Fax:(201) 242-6561

ACCEPTED
...ENTS
...ator Dated:
MAY - 5 2003
... Insecticide,
...ticide Act as
...pesticide,
... EPA Reg. No.
8622-64

BCMW

ACTIVE INGREDIENT(S)	
Ammonia (total)	7.59%
INERT INGREDIENTS	92.41%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
If in Eyes	- Hold eye open and rinse slowly and gently with water for 15-20 minutes. - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. - Call a poison control center or doctor for further treatment advice.
If on Skin, Clothes	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for treatment advice.
If Swallowed	- Call poison control center or doctor immediately for treatment advice. - Have person sip a glass of water, if able to swallow. - Do not induce vomiting unless told to do so by the poison control center or doctor. - Do not give anything by mouth to an unconscious person.
If Inhaled	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-276-0330 or 1-800-BUCKMAN for emergency medical treatment information.	

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
This product is for FORMULATING USE ONLY into EPA registered antimicrobials for the following uses: Pulp and Papermills.

Formulators are responsible for obtaining registrations and preparing labeling in compliance with EPA guidelines for formulations based on this product.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources.

CONTAINER DISPOSAL
PLASTIC: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
METAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Manufactured by
Buckman Laboratories, Inc.
1256 North McLean Blvd.
Memphis, Tennessee 38108, USA
(901) 278-0330 or 1-800-BUCKMAN

EPA Est. No.	1448-TN-1
EPA Reg. No.	1448-
Product Weight	9.59 lbs/gal 1.15kg/l

Net contents are marked on the container.

HMIS / NPCA Ratings

Health	1	Flammability	1	Reactivity	0

Last Revision 12/21/2006

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAR - 6 2007
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1448-432

271

3 of 3

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_x_ Registration
__ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
1448-433	MAR - 6 2007

Term of Issuance: **Conditional**

Name of Pesticide Product: **BUSAN 1215**

Name and Address of Registrant (include ZIP Code):

Buckman Laboratories, Inc.
1256 N. McLean Blv.
Memphis, TN 38108

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No. 1448-433

Signature of Approving Official:

Velma Noble
Product Manager Team-31
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

EPA Form 8570-6

Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Velma Noble
Product Manager 31
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosure:

ANTIMICROBIALS DIVISION

Federal Register Notice Published Seeking Public Comment on Petition to Ban Triclosan. In a Federal Register Notice dated December 8, 2010, EPA made available for review and public comment the "Citizens Petition to the United States Environmental Protection Agency" submitted by Beyond Pesticides and Food & Water Watch. The petition asks the EPA to use its regulatory authority to address concerns with continued use of triclosan in pesticide products. The petitioners claim that the "pervasive and widespread use" of triclosan poses significant risks to human health and the environment. EPA will make a formal response to the petition after reviewing the submissions received in response to the 60-day comment period, which is scheduled to close in February 2011. The FRN and associated petition are in docket EPA-HQ-OPP-2010-0548. (Tim McMahon, 703-308-6342; Rebecca von dem Hagen 703-305-6785)

Registration of Ammonia and Urea-Based Biocide Products Used in Pulp and Paperboard Manufacturing. On December 16, 2010, EPA announced its decision that ammonia (and its salts) and urea-based products should be registered as pesticides when sold or distributed for use in combination with sodium hypochlorite or other chlorine sources as part of biocidal control systems by the pulp and paperboard industry. The Agency received three petitions, each with differing opinions, concerning whether certain products containing ammonia and urea met the definition of "pesticide" under FIFRA, and therefore needed registration, when the products were intended for use by the pulp and paperboard industry as part of a system to control micro-organisms. The docket, which contains documents submitted by the petitioners, public comments, responses to comments, as well as the Agency's response to the petitions and decision documents concerning the Agency's ruling, can be found at www.regulations.gov in Docket ID # EPA-HQ-OPP- 2009-1005. (Melba S. Morrow, 703-308-2716)

Pesticide Products Registered Under the Pesticide Registration Improvement Act (PRIA)

Chemical	Company	EPA Registration	Action Code	Due Date	Completed Date
The Regulatory Branch I granted:					
1,2-Benzisothiazolin-3-one	Arch Chemicals	1258-1336	A540	12/13/10	12/13/10
Martha Terry 703-308-6217					
Caprylic acid	Ecolab	1677-204	A570	12/31/10	12/15/10
Stacey Grigsby 703-305-6440					

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Michael Boucher
McKenna Long & Aldridge
Counsel for Buckman Laboratories
1900 K. Street, NW
Washington, DC 20006

Ms. Karen M. Hansen
Beveridge & Diamond
Counsel for Ashland-Hercules
1350 I Street, NW, Suite 700
Washington, DC 20005-3311

Mr. Seth Goldberg
Steptoe & Johnson LLP
Counsel for Nalco, Inc.
1330 Connecticut Avenue, NW
Washington, DC 20036

I believe Dennis indicated that this decision was already out for public comment for 90 days

Dear Counselors,

The U.S. Environmental Protection Agency has reached a decision regarding the applicability of FIFRA registration requirement to both ammonia (and its salts) and urea products when sold or distributed for use in biocidal control systems in the pulp and paperboard industry along with a chlorine source. This letter provides official notice of that decision and also outlines the actions necessary for Nalco, Inc. to bring its products into compliance with the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Background

Between 2007 and 2009, EPA received three petitions concerning whether certain products containing ammonia and urea met the definition of "pesticide" when the products were intended for use in the pulp and paperboard industry as part of a system to control micro-organisms. The petitions were submitted by three companies – Nalco, Inc. ("Nalco"), Buckman Laboratories ("Buckman"), and Ashland-Hercules ("Ashland") – all of which compete against each other in the marketing of products and services for the control of microorganisms in pulp and paperboard industry manufacturing. Buckman currently holds registrations for ammonia products, BCMW and Busan 1215, and Ashland is a distributor of a registered ammonia product, Spectrum XD3899 Ammonium Bromide Technology, that is manufactured by Ameribrom, Inc.

Nalco does not hold a registration for ammonia, but distributes ammonia and urea products, identified as Nalcon 60620 and Nalcon 60615, respectively, that are so used in the pulp and paperboard industry. These petitions provided differing opinions on whether ammonia or urea products, when sold or distributed for use with sodium hypochlorite or other chlorine sources, as water treatments in the pulp and paperboard industry, should be registered as pesticides.

On May 19, 2010, the Agency published a Federal Register notice (75 FR 28014) and initiated a public comment period relative to these petitions. The Federal Register notice includes a more comprehensive history and other information about this matter. The docket number is EPA-HQ-OPP- 2009-1005. The docket contains documents submitted by the petitioners, as well as public comments.

Issue Presented

The petitions submitted by the various parties present the central issue of whether ammonia and urea products should be registered as biocides when sold or distributed for use in combination with sodium hypochlorite or other chlorine sources as part of biocidal control systems in the pulp and paperboard industry. In terms of the regulatory status of particular products, the petitions question whether NALCO products sold or distributed for such purposes should be required to be registered under FIFRA and whether products registered by Buckman and associated with Ashland (as a distributor) should be required to remain registered under FIFRA when sold or distributed for such purposes.

Specifically, Nalco's petition requested that the Agency reconsider its registration of ammonia products as precursors to chloramine and provide assurance that there is no risk of enforcement during the reconsideration and any transition period. Buckman's petition was filed in response to Nalco's request that the Agency reconsider the registration of ammonia. Buckman's petition further requested that the Agency immediately prohibit further sale and distribution of unregistered ammonia. Ashland's petition presented the same arguments as Buckman for ammonia and further recommended that the Agency take action against the sale and distribution of unregistered urea when used as part of a biocidal system in the pulp and paperboard industry.

Decision

The Agency has determined, based on the activity and fundamental purpose of adding ammonia and/or urea to chlorinated water to facilitate the production of chloramine for biocidal purposes, that Nalcon 60615 and Nalcon 60620 are required to be registered under FIFRA and that Buckman's BCMW and Busan 1215 and Ashland's Spectrum XD3899 Ammonium Bromide Technology must remain registered when sold or distributed for such purposes. This decision letter as well as responses to comments will all be posted to the public docket (EPA-HQ-OPP- 2009-1005). This decision is effective immediately. Instructions for Nalco to achieve compliance with this decision are set forth in the final section of this letter.

Rationale

For the reasons explained below, the Agency concludes that both ammonia and urea products need to be registered as pesticides when sold or distributed for use in combination with chlorine in biocidal control systems to address microbial pest problems in the pulp and paperboard industry.

EPA has carefully reviewed the available information concerning how ammonia and urea function as part of biocidal control systems in the pulp and paperboard industry, as well as how Ashland, Buckman, and Nalco intend their ammonia and urea products to be used. Neither ammonia nor urea, by itself, has pesticidal activity. Nonetheless, the ways in which the three companies market their ammonia and urea products, as well as the known and intended uses of those products in the pulp and paperboard industry, bring those products within the definition of a pesticide. Specifically, EPA has determined that the three companies directly state or imply and intend that their products should be added to chlorinated water as part of a biocide control system in the pulp and paperboard industry where the material will interact with chlorine that is also added to the water. Once the ammonia or urea is added, it reacts with chlorine to ultimately form a new chemical substance, chloramine. (Urea in the presence of sodium hypochlorite or a chlorine source forms a chlorourea, which undergoes further chemical reaction to form chloramine.) As the three companies know, the chloramine formed following the addition of ammonia and urea to chlorinated water has pesticidal activity against microbial organisms. Moreover, compared to chlorine, chloramine exhibits extended antimicrobial activity.

In reaching its conclusion that the products under review are pesticides, EPA relies on the statutory definition of "pesticide" in FIFRA 2(u), as well as its regulations in 40 CFR 152.15(a)(1), 40 CFR 152.15(c) and 40 CFR 153.125(a)(2). FIFRA section 2(u) defines a "pesticide" in pertinent part as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest . . . ." EPA has interpreted this statutory term in regulations at 40 CFR 152.15, which states:

> No person may distribute or sell any pesticide product that is not registered under the Act...A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:
> (a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):
> (1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or . . .
> (c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

Finally, EPA's conclusion also takes into consideration the regulation in 40 CFR 153.125(a)(2), which sets forth criteria for determining whether a substance has pesticidal activity. The regulation states that an ingredient will be considered to be an active ingredient if it:

> . . . has the ability to elicit or enhance a pesticidal effect in another compound whose pesticidal activity is substantially increased due to the interaction of the compounds. Compounds which function simply to enhance or prolong the activity of an active ingredient by physical action, such as stickers or other adjuvants, are not generally considered to be active ingredients.

Chloramine and chlorine, as part of a biocidal control system, destroy microbial pests in pulp and paperboard industry manufacturing; each is clearly a "pesticide" under FIFRA section 2(u). Ashland, Buckman, and Nalco are selling their ammonia and urea products for use as part of a biocidal control system in the pulp and paperboard industry. The directions for use on these products indicate that they should be added to the water systems, which already contain chlorine, to prolong the antimicrobial activity of the chlorine in the system. Although not specifically stated in the use directions, this occurs as a result of the chemical reaction between the chlorine and either the ammonia or urea and not as a result of physical action. Thus, EPA finds the three companies are selling substances for which they state or imply that their products used in combination with a chlorine source in water can be used as part of a biocidal control system to control microbial pests in pulp and paperboard industry manufacturing. Under 40 CFR 152.15 (a)(1), such products are considered pesticides. Likewise, EPA finds that the three companies know their products are being used in the manner described above, and by specifically marketing their products to customers in the pulp and paperboard industry, they fall under the provision in 40 CFR 152.15(c).

Ammonia, by itself, does not have any pesticidal activity, but cannot be characterized as a stabilizer as was suggested by some parties. A stabilizer is a chemical compound that does not change the characteristics of an active ingredient with which it is mixed. In the presence of sodium hypochlorite or a chlorine source, both ammonia and urea react to ultimately form chloramine, which itself is a different chemical compound from chlorine or sodium hypochlorite. Based on the fact that ammonia and urea are consumed in an irreversible chemical reaction and that a new chemical is formed, which possesses pesticidal activity; neither ammonia nor urea can be classified as stabilizers.

Ammonia does not perform in a similar way to citric acid, acetic acid, and cyanuric acid. Unlike ammonia, the use of citric acid, acetic acid, and cyanuric acid as halogen stabilizers does not result in the formation of a new chemical which has a different spectrum of pesticidal activity. Ammonia does not have the same activity when combined with sodium hypochlorite or a chlorine source as that ascribed to chemicals that are used to stabilize other pesticides to prevent their degradation in the presence of sunlight.

Further, EPA finds that the interaction of ammonia or urea with chlorine prolongs and therefore substantially increases the pesticidal activity of chlorine. EPA notes that, unlike ingredients (such as stickers and other adjuvants) which prolong the activity of a pesticidally active chemical by physical action, the ammonia and urea act by causing a chemical reaction with chlorine or a chlorine source to ultimately form chloramine. Therefore, ammonia and urea meet the criterion in 40 CFR 153.125(a)(2) for identifying a pesticidally active substance.

In light of all of the above, EPA concludes that the ammonia and urea products sold by Ashland, Buckman, and Nalco to the pulp and paperboard industry for use in controlling microbial pests in water systems are pesticides and must be registered (or remain registered) under FIFRA.

Required Actions

In light of the foregoing, and within 30 days of Nalco's counsel's receipt of this letter, Nalco must submit full application packages for new active ingredients for Nalcon 60615 and Nalcon 60620 to satisfy this determination that FIFRA registrations are required for these products.

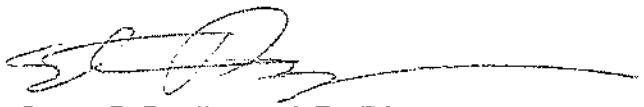
The Application for Pesticide Registration must include the following:

Application for registration (Form 8570-1)
Confidential Statement of Formula (Form 8570-4)
Certification with Respect to Citation of Data form (Form 8570-34)
Data Matrix (Form 8570-35)
Copies of proposed label
Data – The following data must be submitted/addressed:
- Chemistry data on the active ingredient as well as the proposed product
- Six acute toxicity studies on the active ingredient as well as the proposed product
- 90 day subchronic study
- Developmental toxicity study
- 2-generation reproductive study
- Mutagenicity battery (3 studies)
- Hydrolysis study
- Avian oral LD 50 study
- Fish Acute LC 50 study
- Aquatic invertebrate LC 50 study
- Residue studies to determine chloramine levels that may occur in pulp and paperboard.

This letter does not constitute permission for Nalco to continue to distribute or sell such products unless and until they are registered. The continued distribution or sale of those products constitutes a violation of FIFRA. Petitioners Ashland and Buckman have asked EPA to take enforcement action against Nalco for selling unregistered pesticides. EPA's Office of Enforcement and Compliance Assistance will respond separately to these requests.

For further information or clarification on the registration process for the Nalco products, please contact Joan Harrigan-Farrelly, Director of the Antimicrobials Division, at Harrigan-Farrelly.Joan@epa.gov or call 703-308-6468.

Sincerely,



Steven P. Bradbury, Ph.D., Director
Office of Pesticide Programs

cc: Rosemarie Kelly, EPA Office of Enforcement and Compliance Assurance
Philip J. Ross, EPA Office of General Counsel
Joan Harrigan-Farrelly, Antimicrobials Division Director

Fw: New AI Ammonium Sulfate docket

Tracy Lantz to: Caroline Klos 01/06/2011 04:26 PM

Cc: Dennis Edwards, Velma Noble

Attached below is the signed and scanned docket verification form.
Also attached is my notice of receipt for a new AI batching information form.

notice of receipt for new ai_NH4 Sulfate.docx

Please let me know if you have any questions. I will be in the office on Friday.

Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

----- Forwarded by Tracy Lantz/DC/USEPA/US on 01/06/2011 04:19 PM -----

From:	cts/cts/QP/USEPA/US@EPA
To:	Tracy Lantz/DC/USEPA/US@EPA
Date:	01/06/2011 04:09 PM
Subject:	New AI Ammonium Sulfate docket

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device. [Untitled].pdf

U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES (OPPTS)
1200 Pennsylvania Avenue, N.W. , Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action: Ammonium Sulfate Registration of New Active Ingredient		
RIN #: 2070-	**Docket ID #:** EPA-HQ-OPP-2011-0019	**FRL#:**
Docket Title: Ammonium Sulfate Registration of New Active Ingredient		
Contact Information:	**Name:** Tracy Lantz	**Phone:** 703 308 6415
Legacy Information:		

Program Lead's Verification: I have reviewed the docket and verified the following:

All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.

Documents containing copyrighted, CBI or otherwise protected information have been identified to allow for "special" processing by the docket.

The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.

✓ Comments: No supporting materials

Date: 1/6/11	Initials: TJL	Phone: 703 308 6415

Docket Manager's Verification and Sign-off: I hereby confirm the following:

The Docket ID # identified above matches our records.

The documents identified in the attached Docket Index have been received by the Docket.

The documents have been properly processed for inclusion in EPA Dockets, as appropriate.

The documents either already are in the docket or are being process for inclusion in the docket.

Comments: No Supports

Date: 1/6/11	Signature: Cynthia Peters	Phone: 308-5805

Program Lead's Certification: I hereby certify that:

I have completed the verification above.

I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.

I have obtained the DM's sign-off.

The docket is complete and ready for public release.

Comments:

Date: 1/7/11	Signature: Tracy Lantz	Phone: 703 308 6415

Attachment:

Notice of Receipt for a New Active Ingredient batching information

In addition to the information below you will need to email to BPPD is the scanned copy of the OPP Docket Certification/Verification form filled in/signed by you and the OPP Docket staff (Anthia Peters).

Docket Number: EPA-HQ-OPP-2011-0019

RAL/PM Name: Tracy Lantz

RAL/PM Email: Lantz.tracy@epa.gov

RAL/PM Phone: (703) 308-6415

Fill out the following paragraph:

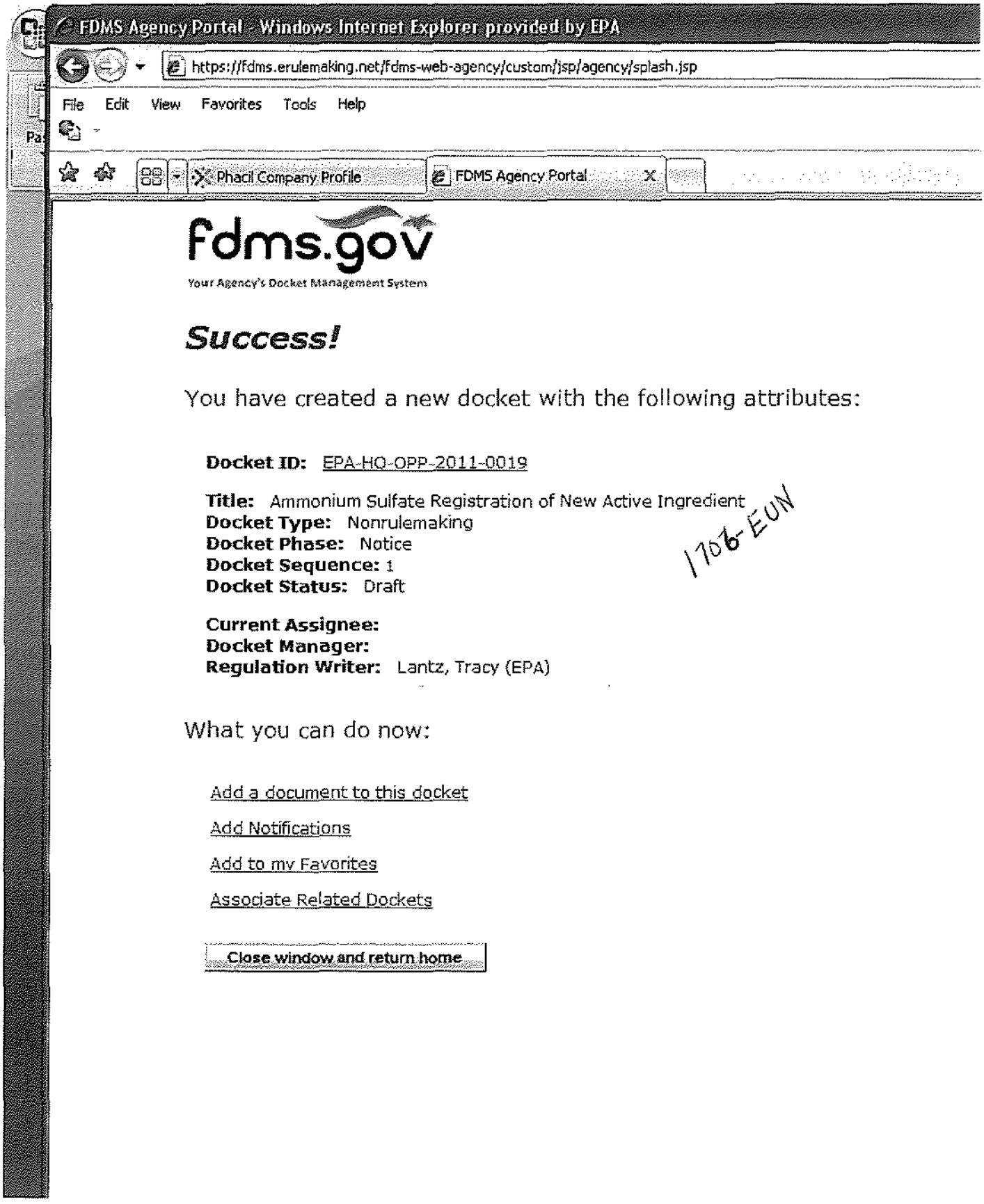
File Symbol: [1706-EUN]. *Applicant:* [Nalco Company, 1601 West Diehl Road, Naperville, IL 60563]. *Product name:* [Nalco 60620]. *Active ingredient:* [antimicrobial] and [Ammonium Sulfate] at [20 %]. *Proposed classification/Use:* [pulp and papermill water systems.] [[Tracy Lantz, (703) 308-6415, Lantz.tracy@epa.gov; EPA-HQ-OPP-2011-0019]

DOCKETS CREATED

Latasha White to: Tracy Lantz

Cc: Anthia Peters

01/05/2011 04:23 PM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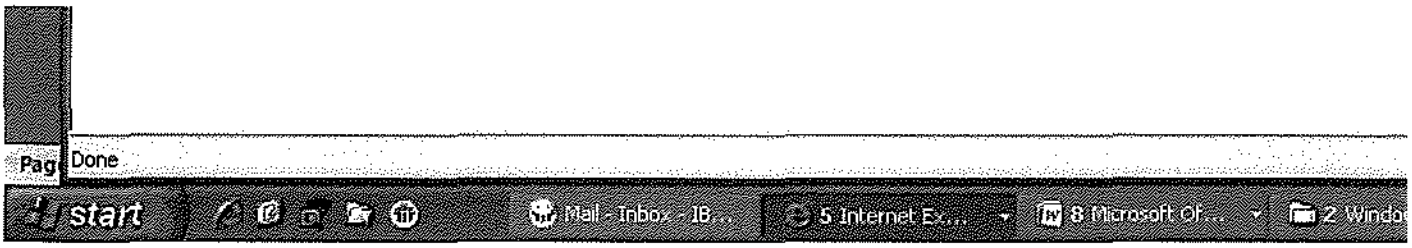
File Edit View Favorites Tools Help
Phacil Company Profile
FDMS Agency Portal
fdms.gov
Your Agency's Docket Management System
Success!
You have created a new docket with the following attributes:
Docket ID: EPA-HQ-OPP-2011-0019
Title: Ammonium Sulfate Registration of New Active Ingredient
Docket Type: Nonrulemaking
Docket Phase: Notice
Docket Sequence: 1
Docket Status: Draft
Current Assignee:
Docket Manager:
Regulation Writer: Lantz, Tracy (EPA)
1706-EUN
What you can do now:
Add a document to this docket
Add Notifications
Add to my Favorites
Associate Related Dockets
Close window and return home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BUCKMAN LABORATORIES, INC.'S REPLY TO NALCO COMPANY'S DEC. 4, 2007 REQUEST THAT EPA RECONSIDER ITS REGISTRATION FOR AMMONIA PRODUCTS AS PRECURSORS TO CHLORAMINE USED IN WATER TREATMENT

AND

BUCKMAN LABORATORIES, INC.'S REQUEST THAT EPA IMMEDIATELY PROHIBIT FURTHER DISTRIBUTION AND SALE OF UNREGISTERED AMMONIA FOR WATER TREATMENT

Michael Boucher

McKENNA LONG & ALDRIDGE LLP
1900 K Street, NW
Washington, D.C. 20006
(202) 496-7729

Counsel to

Buckman Laboratories, Inc.

September 2, 2008

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

I. Overview

Nalco Company's (hereinafter, "Nalco's") December 4, 2007 "Request That EPA Reconsider Its Registration for Ammonia Products as Precursors to Chloramine Used in Water Treatment and Provide Assurance That There Is No Risk of Enforcement during the Reconsideration and Any Necessary Transition Period" (hereinafter, "Nalco's Petition") is a tirade against EPA's registrations of BCMW (EPA Reg. No. 1448-432) and Busan 1215 (EPA Reg. No. 1448-433), Buckman Laboratories, Inc.'s (hereinafter, "Buckman's") manufacturing-use and end-use ammonia products, respectively. The violence of Nalco's protest tacitly acknowledges Nalco's need to register its own current end-use ammonia product, Nalcon 60620, because Nalcon 60620 and Busan 1215 essentially have the same composition, are used by the same industrial users in the same manner for water disinfection, and are considered interchangeable products in the marketplace. Nalco's Petition ignores the unknown and potentially unreasonable risks presented by the ongoing use of unregistered ammonia to produce monochloramine (hereinafter, "MCA"), including human health risks from unapproved residues of MCA in paper used for food packaging and toxicity to aquatic organisms from MCA residues in industrial waste water.[1] Not surprisingly, Nalco also ignores the significant and ongoing damage being done unfairly to the commercial value of Buckman's ammonia registrations – and to Buckman's ability to recoup its investment in such registrations – by Nalco's ongoing sale of unregistered ammonia with EPA's "temporary" permission, which has lengthened to seven months with no end in sight.

[1] Coincidentally, we have obtained a pre-publication *Federal Register* notice, attached hereto as Exhibit "A," which reports that Zentox Corporation has petitioned the Food and Drug Administration to use MCA as a food additive, specifically, "as an antimicrobial agent in poultry process chiller water" (emphasis added), even though EPA has not registered MCA or ammonia for any such use. This food additive petition underscores the urgent need for EPA to publicly affirm its jurisdiction over MCA – specifically, to prohibit the further distribution and sale of unregistered ammonia for *any* water treatment use, including poultry processing.

To justify the status quo, Nalco offers a series of increasingly erratic and unfocused arguments. Initially, Nalco alleges that ammonia cannot be registered, because it is not an active ingredient (Nalco's Petition at 6-7), but later flip-flops and acknowledges that, in fact, EPA can register a precursor of an active ingredient, where registration of the active ingredient itself is not practical (Nalco's Petition at 9) – exactly as EPA has done with BCMW and Busan 1215, because the registration of MCA itself for water treatment is impractical. Then, Nalco agrees that combining ammonia and sodium hypochlorite produces MCA (Nalco's Petition at 4), in a chemical reaction known since the early 1900s, but alleges that MCA is not an active ingredient that is separate from "chlorine" (hypochlorous acid) (Nalco's Petition at 8-9, 11), even though the production of MCA is a reaction that is not considered reversible (*i.e.*, once formed, MCA does not readily break down into, or otherwise produce, ammonia and hypochlorous acid/hypochlorite ions), and despite that EPA and industry recognize MCA as a distinct active ingredient with valuable properties that are different from those of hypochlorous acid. Nalco also plays variations on the foregoing theme, specifically, that ammonia "sequesters" and releases "chlorine" by a novel chemical process that Nalco never explains (Nalco's Petition at 4, 6-7, 11-12), and that ammonia is only an adjuvant used with "chlorine" and, thus, requires no registration (Nalco's Petition at 15), even though ammonia reacts completely with sodium hypochlorite to form a new active ingredient, MCA, and, thus, does not hold or release hypochlorous acid and does not resemble any adjuvant.

For the foregoing reasons, as articulated and explained in this petition, we respectfully request pursuant to section 553(e) of the Administrative Procedures Act (5 U.S.C. § 553(e)) that EPA deny Nalco's Petition and immediately prohibit further distribution and sale of unregistered ammonia for water treatment. Nalco has asked for time to register ammonia but neither needs

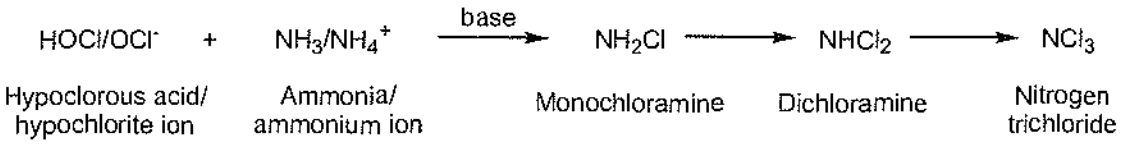
nor deserves any additional time. Nalco has had notice of EPA's policy on the registration of ammonia for water treatment since the Agency's registration of Buckman's ammonia products on March 6, 2007. Since then – a period of 18 months – Nalco has found ample time to make two lengthy and duplicative submissions and one responsive submission to EPA in order to subvert the Agency's registration of Buckman's ammonia products. Neither of Nalco's original filings ever had a likelihood, much less a *certainty*, of persuading EPA to revoke its considered registrations of ammonia, which Nalco knew at the time of its filings. Indeed, as recently as July 15, 2008, the Agency amended Buckman's registration of Busan 1215 to add a new use (industrial water systems), which suggests no intent by EPA to grant either of Nalco's original requests to revoke Buckman's ammonia registrations. Accordingly, in addition to filing petitions with EPA, Nalco also should have filed or, at a minimum, prepared itself fully to file an application to register ammonia sometime during the past 18 months. If, as it appears, Nalco has chosen instead to focus wholly on a speculative petition effort intended to manipulate EPA into allowing Nalco to remain on the market without an ammonia registration and, thereby, to continue to compete with Buckman unfairly and, specifically, to erode its customer base, the Agency should not now reward Nalco for its gamesmanship with any additional time to register ammonia.

In preparing this petition on behalf of Buckman, we consulted with scientists and regulatory consultants at Technology Sciences Group Inc., namely, Dr. Robert Stewart, Vice President and Managing Director, and Dr. David Brookman, Director of Environmental Chemistry. Drs. Stewart and Brookman have reviewed and concur in our technical representations in this petition.

II. **Both Nalco and Buckman sell ammonia for use in proprietary systems in which ammonia and sodium hypochlorite react to form MCA, which is the active ingredient supplied by each system for water treatment.**

Use of either Nalco's or Buckman's end-use ammonia product, as labeled, generates the same main active ingredient, MCA (monochloramine), which is formed by a chemical reaction that occurs at the time of use. The general reaction is as follows:

Figure 1

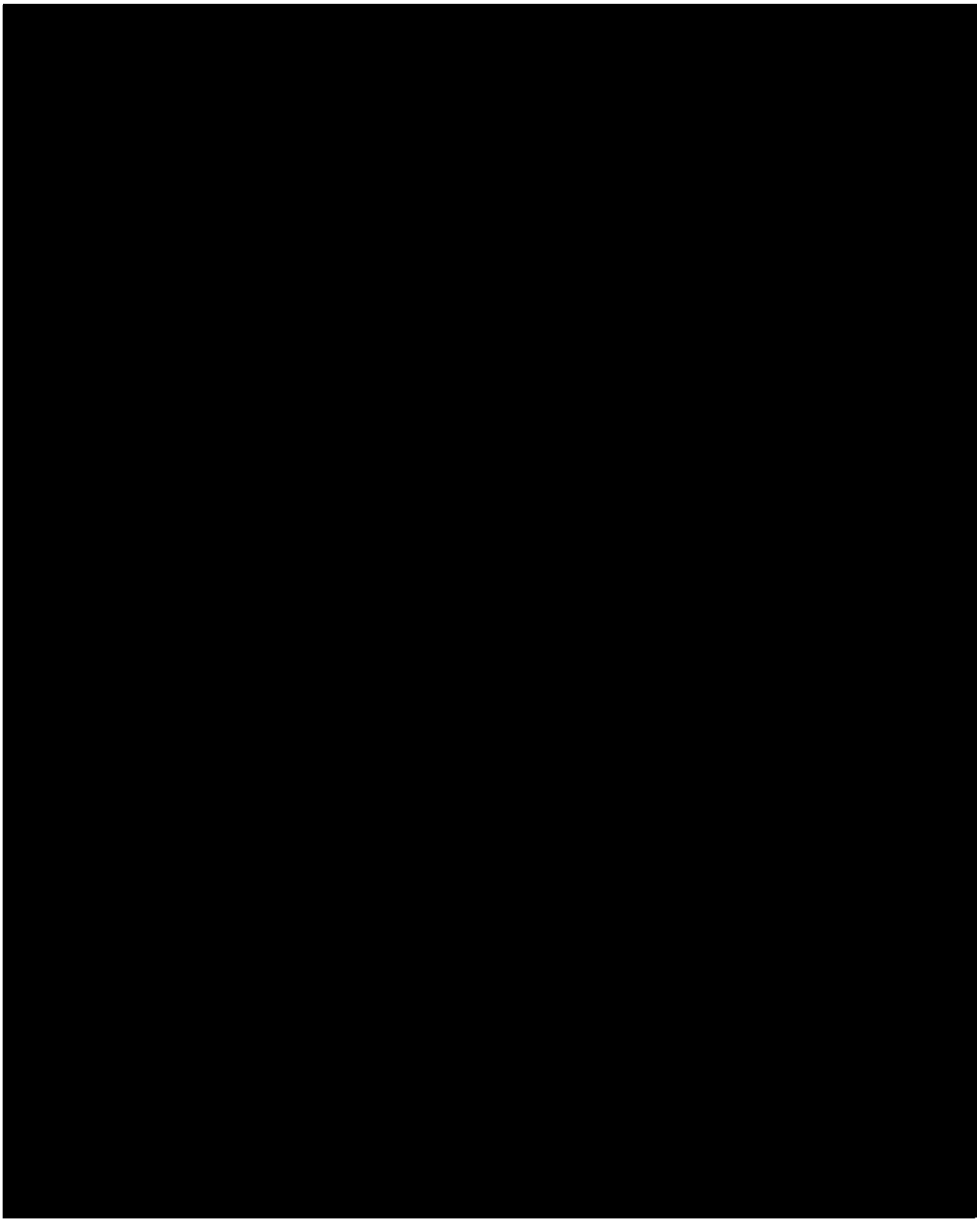


The reaction is normally terminated at the stage where MCA is formed, but dichloramine and nitrogen trichloride also may occur.

The nominal active ingredient in Nalco's end-use ammonia product (Nalcon 60620) is "ammonium sulfate" and in Buckman's end-use ammonia product (Busan 1215) is "ammonia (total)," which derives from an aqueous mixture of ammonia and ammonium sulfate. Therefore, both products provide ammonia or ammonium ions in the reaction shown in Figure 1 above, and both lead to the in-situ generation of one or more chloramines.

According to its label, attached hereto as Exhibit "B," Nalcon 60620 is an unregistered formulation consisting of 20% ammonium sulfate and 80% "constituents ineffective as spray adjuvants," presumably water. Nalco sells Nalcon 60620 as part of its "OxiPRO™ Deposit Control Technology" and, specifically, for use in Nalco's "OxiPRO Feed System," which is illustrated and described in a Nalco proposal and a Nalco slide presentation attached hereto as Exhibits "C" and "D," respectively. Nalco's label for Nalcon 60620 and Nalco's materials on the OxiPRO Feed System describe a process in which a Nalco technician adds Nalcon 60620 to

Nalco Briefing for Steve Bradbury
1/26/11



Internal deliberative

This 3 letter #1

Fw: Ashland Inc. Comments on EPA's FIFRA Registration Requirements for Nalco's Unregistered Biocides

Joan Harrigan-Farrelly to: Melba Morrow, Dennis Edwards, Tracy Lantz 01/25/2011 05:39 PM

Sorry Melba

[redacted]

Here it is.

Joan

----- Forwarded by Joan Harrigan-Farrelly/DC/USEPA/US on 01/25/2011 05:39 PM -----

[redacted]

From: "Karen M. Hansen" <KHansen@bdlaw.com>
To: Joan Harrigan-Farrelly/DC/USEPA/US@EPA
Cc: Steven Bradbury/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA, Rosemarie Kelley/DC/USEPA/US@EPA, <wilson.kimberly@epa.gov>
Date: 01/20/2011 09:46 AM
Subject: Ashland Inc. Comments on EPA's FIFRA Registration Requirements for Nalco's Unregistered Biocides

Dear Joan,

Attached please find brief comments on behalf of Ashland Inc. regarding the FIFRA data requirements applicable to any pesticide registration application(s) that Nalco is or may be pursuing for its unregistered ammonium sulfate and urea products that were the subject of the December 16, 2010 letter from the Office of Pesticide Programs (OPP). In addition to asking that your office consider the points raised in these comments, Ashland also respectfully requests a meeting with the OPP team that is or will be working on Nalco's application(s), at your earliest convenience, so that we may discuss certain scientific and technical issues associated with EPA's review of the chemistries associated with such products. Thank you in advance for your consideration of these comments and our meeting request. Please feel free to contact me with any questions and/or to schedule a time when Ashland and EPA can meet.

Best regards,

Karen

Karen M. Hansen
Beveridge & Diamond, P.C.
1350 I Street, NW
Suite 700
Washington, D.C. 20005
(202) 789-6056

khansen@bdlaw.com 2011-01-20 KMH To J. Harrigan-Farrelly, EPA, Re Ashland Response To OPP_s 2010-12-16 Letter.PDF

Internal deliberative

BEVERIDGE & DIAMOND PC

Karen M. Hansen
1350 I Street, N.W.
Suite 700
Washington, D.C. 20005-3311
Direct: (202) 789-6056
Fax: (202) 789-6190
khansen@bdlaw.com

January 20, 2011

Via Electronic Mail

Joan Harrigan-Farrelly
Director, Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
2777 South Crystal Dr., One Potomac Yard
Arlington, Virginia 22202

Re: OPP's December 16, 2010 Letter Regarding the FIFRA Registration Requirements Applicable to Nalco's Unregistered Ammonium and Urea Biocides

Dear Ms. Harrigan-Farrelly:

On behalf of Ashland, Inc. ("Ashland"), I am writing to follow-up on two specific aspects of the Office of Pesticide Programs' December 16, 2010 letter confirming that Nalco's unregistered urea and ammonium sulfate products are biocides which need to be registered under FIFRA and that the continued distribution or sale of these unregistered urea and ammonium sulfate products constitutes a violation of FIFRA. In particular, Ashland seeks to ensure that EPA fully applies the relevant data requirements of FIFRA to both of Nalco's unregistered biocides and does not limit the Agency's review or Nalco's data obligations to those items listed in the December 16, 2010 letter.

1. Nalco's Applications Must Satisfy All of EPA's Data Requirements Associated With Aquatic Non-Crop Biocides

OPP's letter states that Nalco must submit "full application packages for new active ingredients" for both products, yet identifies only 11 types of data that must be submitted or addressed in each of Nalco's applications for registration.[1] Ashland is concerned that the

[1] The data requirements identified by OPP in its December 16, 2010 letter are: (1) chemistry data on the active ingredient and proposed product; (2) six acute toxicity studies on the active ingredient and proposed product; (3) a 90-day subchronic study; (4) a developmental toxicity study; (5) a two-generation reproductive study; (6) a mutagenicity battery (three studies); (7) a hydrolysis study; (8) an avian oral LD 50 study; (9) a fish acute LC 50

Agency's listing of a subset of applicable data requirements not in any way limit Nalco's obligation to satisfy the full range of data requirements that apply to applications for new products containing ammonium sulfate or urea that produce two different biocides, chloramines and chlorourea, respectively. As you know, Nalco's proposed use of urea to produce a chlorourea biocide for use at pulp and paper mills is not addressed by any prior FIFRA registration and should be reviewed carefully consistent with EPA's regulations.

In proposing its new data requirements for antimicrobial products in 2008, EPA stated that the Agency's FIFRA "data requirements illustrate the questions the registrant will need to answer about the safety of the pesticide product before the Agency can register it." 73 Fed. Reg. 59382, 59386 (Oct. 8, 2008).[2] The Agency's requirements for the registration of antimicrobial products provide that the "pulp and papermill systems" use pattern corresponds with the general use pattern for "aquatic noncrops." 40 C.F.R. Part 161, App. A(9). Accordingly, any Nalco application for a pulp and paper mill biocide product must at a minimum demonstrate satisfaction of each requirement identified by EPA at 40 C.F.R. Part 161 as "Required" (and, as appropriate, "Conditionally Required") to support the registration of a new aquatic nonfood biocide. *See, e.g.*, 40 C.F.R. § 152.90(a) (requiring follow-on applications to fulfill all of the data requirements applicable to a product and its use patterns as if it were "being proposed for registration under FIFRA Section 3(c)(5) for the first time.").[3]

Ashland respectfully asks that you clarify that the scope of the requirements applicable to Nalco's products includes all data requirements associated with aquatic noncrop biocides, whether or not specifically highlighted by EPA' December 16, 2010 letter.

2. EPA Must Evaluate the Full Non-Target Exposure Profile of Chlorourea

EPA's December 16 letter indicates that Nalco must submit chemistry data and the six required acute toxicity studies using both the "active ingredient" and the "proposed product." In the context of Nalco's ammonium sulfate product (Nalcon 60620), EPA's letter correctly identifies the *in situ* generated biocide that forms upon reaction of that product with sodium hypochlorite as chloramine. However, the actual *in situ* generated biocide that is formed and may be released into the environment upon reaction of urea (such as Nalcon 60615) with hypochlorite is chlorourea. The December 16, 2010 letter appears to confuse the two products as

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study; (10) an aquatic invertebrate LC 50 study; and (11) residue studies to determine chloramine levels that may occur in pulp and paperboard.

[2] In discussing the newly proposed antimicrobial requirements, EPA expressly advised potential applicants for new registrations "to evaluate their products in light of the proposed requirements." 73 Fed. Reg. 59388. Accordingly, EPA should consider the implications of its proposed requirements on Nalco's applications.

[3] *See also id.* at § 152.86(d)(ii) (requiring that applications be supported by the "types of data that EPA would require to be submitted if the application sought the initial registration under FIFRA section 3(c)(5) of a product with composition and intended uses identical or substantially similar to the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application").

involving similar chemistries rather than recognize them as distinct biocides warranting separate evaluation.

In particular, OPP's December 16 letter inaccurately states that the chlorourea generated upon reaction of Nalco's urea product with sodium hypochlorite "undergoes further chemical reaction to form chloramine." This is not technically accurate, as demonstrated in the record before EPA. Therefore, the test substance that Nalco must use for EPA's data requirements associated with environmental fate and toxicity to non-target organisms for Nalco's urea product is chlorourea, not chloramine.

Requiring that Nalco submit data using chlorourea to evaluate all potential human and environmental exposure pathways associated with Nalcon 60615 is critical because EPA has never previously evaluated the possible effects of exposure to chlorourea in any context under FIFRA. In fact, chlorourea is not well-studied by any U.S. regulatory agency in terms of its most basic environmental fate and toxicity profile. EPA's 2002 Tolerance Reassessment Evaluation Decision ("TRED") for urea, which relied largely on publicly available literature and identified no risk concerns for urea within the limits of EPA's existing tolerance exemptions, did not consider *any* risks associated with the generation of chlorourea. Therefore, the data in the TRED is insufficient to assess the risks associated with chlorourea.

For this reason, EPA's evaluation of any Nalco application for a urea product with pulp and paper mill uses must include full consideration of data needs for assessment of human and other non-target organism impacts resulting from potential exposure to chlorourea. Potential exposure pathways that must be considered, for example, include:

- any residues of chlorourea in paper that may migrate into packaged food and thus require a formal food contact substance notification to the U.S. Food and Drug Administration ("FDA");
- any residues of chlorourea in mill effluent water that may migrate into drinking water and thus require a pesticide tolerance or tolerance exemption from EPA;
- the persistence of chlorourea (and its transformation products) in the environment;[4]
- potential impacts of chlorourea on non-target aquatic plants;[5]

[4] *See, e.g.*, EPA Guideline No. 835.2120 (Hydrolysis).

[5] EPA's proposed antimicrobial data requirements make clear that testing on green algae is required even for products associated with low environmental exposure. 73 Fed. Reg. 59382, 59416 (Oct. 8, 2008). The results of this test can then be used by EPA to determine whether other aquatic plant growth studies (including duckweed) may be required.

- potential impacts of chlorourea on fish and aquatic invertebrates;[6]
- potential impacts of chlorourea on microorganisms found in biological wastewater treatment systems;[7] and
- mutagenicity potential and other genotoxic effects of chlorourea.

FIFRA § 3(a) requires EPA to review pesticides for registration with sufficient information in order to prevent "unreasonable adverse effects on the environment." Accordingly, EPA's evaluation of Nalco's applications must include consideration of all potential exposure pathways for chloramines and chlorourea, in addition to the full set of data requirements associated with the Agency's assessments of pulp and paper mill biocides containing urea and ammonium sulfate. EPA should not approve any Nalco registrations for such products unless and until Nalco has addressed all applicable data requirements and the Agency possesses and has fully evaluated the information it needs to make the required determinations.

Ashland respectfully requests a meeting in the near future with the OPP team that is or will be reviewing any registration applications by Nalco for its ammonium sulfate and/or urea products. Ashland remains concerned about the safety issues associated with these products since EPA has not reviewed these risks under FIFRA, and we would like to discuss with you the distinct chemistries involved with creating chloramines and chlorourea and the implications of this factual difference for the data that EPA should require of Nalco. We also respectfully request a written response to these comments so we may stay informed about further EPA data requirements applicable to Nalco's unregistered biocides.

Thank you in advance for your attention to these comments and our request for a meeting.

Sincerely,

Karen M. Hansen /MEH

Karen M. Hansen

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[6] *See, e.g.*, EPA Guideline Nos. 850.1075 (Fish Acute LC 50) and 850.1010 (Aquatic Invertebrate LC 50).

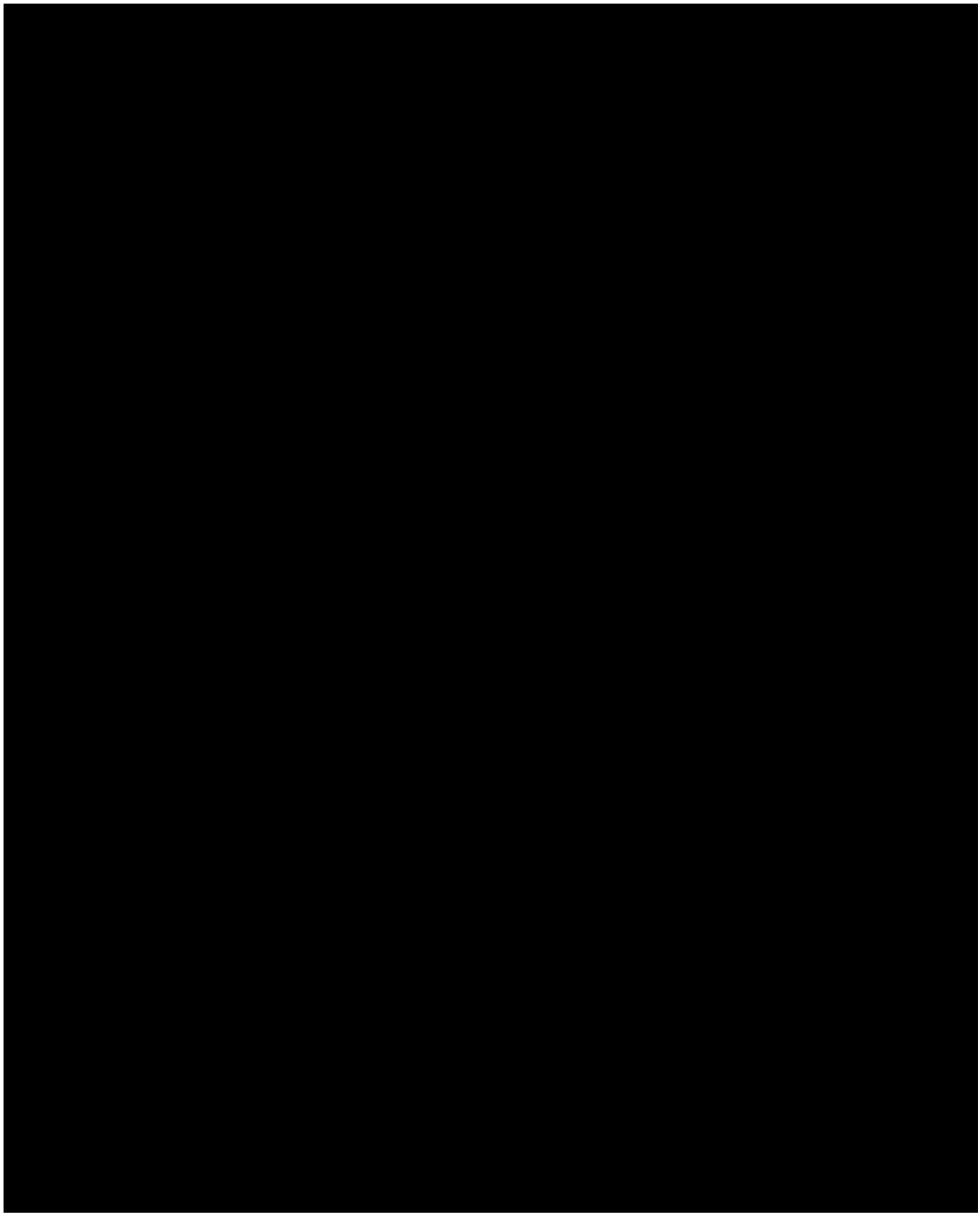
[7] To address this concern, EPA has already proposed requiring an activated sludge respiration study (EPA Guideline No. 850.6500) for any product with proposed use in once-through industrial processes and water systems – the specific use pattern corresponding to Nalco's products. 73 Fed. Reg. at 59410.

cc: S. Bradbury, Ph.D. (OPP)
R. Kelly (OECA)
P. Ross (OGC)

Ammonia Application Time Line

Internal deliberative

Ammonia Time Line



Internal deliberative

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 14, 2011

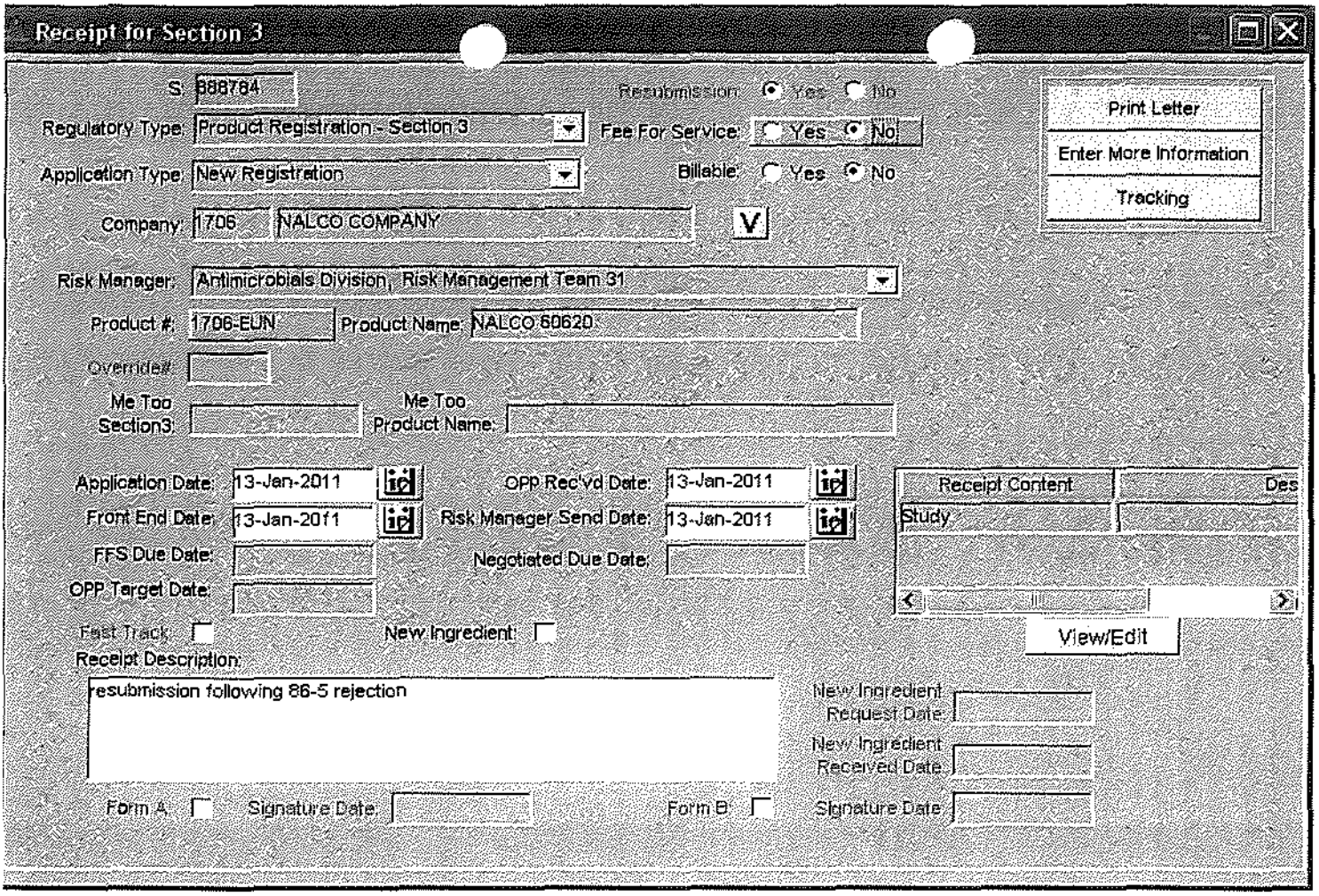
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

WILLIAM S. UTLEY
NALCO COMPANY
1601 WEST DIEHL ROAD
NAPERVILLE, IL 60563-1198

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 13-JAN-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 888784
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 1706 NALCO COMPANY
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 1706-EUN
Product Name: NALCO 60620
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 13-Jan-2011
OPP Rec'vd Date: 13-Jan-2011
Front End Date: 13-Jan-2011
Risk Manager Send Date: 13-Jan-2011
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
resubmission following 86-5 rejection
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

STEPTOE & JOHNSON LLP
ATTORNEYS AT LAW

483512-00

WRITER'S DIRECT DIAL
202.429.3095

1330 Connecticut Avenue, NW
Washington, DC 20036-1795
Tel 202.429.3000
Fax 202.429.3902
steptoe.com

December 23, 2010

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Velma Noble, PM 31

Subject: Nalco 60620, EPA File Symbol 1706--
Application for Registration of New Product (Secondary Registration)

Dear Velma:

On behalf of Nalco Company, enclosed please find an application for registration of Nalco 60620, an end-use product containing a new active ingredient, ammonium sulfate. The proposed registration for Nalco 60620 is for use in an in-situ generating system for use in pulp and paper mills.

Nalco 60620 is substantially similar to an existing registered product, Busan 1215, EPA Reg. No. 1448-433. That fact is substantiated by statements made by Buckman, registrant of Busan 1215 (attached to this letter and available at EPA-HQ-OPP-2009-1005-0003 at electronic pages 4 and 7). Nalco believes that the correct identification of the active ingredient is ammonium sulfate, which is what is used to formulate this product. While ammonium sulfate (CAS RN 7783-20-2) does dissociate in aquaeous solution to a degree, the product does not fully dissociate to ammonium hydroxide (or aqua ammonia) (CAS RN 1336-21-6), nor does it convert to ammonia (CAS RN 7664-41-7, EPA PC 5302), which is a gas. Regardless of whether the ammonium ion from ammonium sulfate is expected to stabilize chlorite from sodium hypochlorite and monochloroamine, the product for which this submission is made contains an aqueous solution of ammonium sulfate. As such, Nalco has identified the active ingredient as ammonium sulfate and has developed this application on that basis. Should the Agency believe otherwise, Nalco would be glad to discuss it further. Nalco has conducted the necessary testing with ammonium sulfate and/or referenced data on that compound.

Despite the identification of the active ingredient as ammonium sulfate, Nalco is relying upon existing Agency decisions regarding this compound and its dissociation products, which have been used to support multiple decisions. In particular, see the tolerance reassessment for mineral acids and associated salts (EPA-HQ-OPP-2002-0162-170), RED and registration review decision documents on mineral acids, decisions regarding related compounds such as ammonium nitrate (inert ingredient for food use), and decisions regarding ammonia and ammonium ion from similar compounds, determination by FDA that ammonium sulfate is a GRAS material when used as a direct food additive (see 21 CFR 184.1143).

This is a PRIA action (Action Code A420). Documentation of prepayment of the PRIA fee is attached to this letter.

Nalco Company is conducting a storage stability and corrosion characteristics study to address OPPTS guidelines 830.6317 and 830.6320. A final report will be submitted upon completion of the study. We request that submission of the final storage stability report when completed be a condition of registration.

Enclosed with this application please find:

1. EPA Form 8570-1, application form
2. EPA Form 8570-34, Certification with Respect to Citation of Data
3. EPA Form 8570-35, Data matrix (Agency Use and Public File Copies)
4. EPA Form 8750-4, Confidential Statement of Formula
5. Five (5) copies of the proposed labeling
6. Transmittal Document
7. Three (3) copies of each submitted study

Please contact me if you have any questions or require any additional information.

Sincerely,

Juli Mann

Juli Mann
Paralegal Specialist
jmann@steptoe.com

TRANSMITTAL DOCUMENT

Submitter

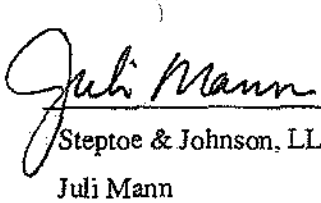
Nalco Company
1601 West Diehl Road
Naperville, IL 60563

Regulatory action in support of which this package is submitted
Nalco 60620, EPA Registration No. 1706-
New product registration EUN

Transmittal Date
December 23 2010

Submitted Studies

	MRID	
---		Administrative Materials
Doc 1	**48340801**	Mann, J. 2010. Nalco 60620: Product Identity and Composition (Group A). Report No. 60620-Group A. 20 pages. Contains Confidential Business Information.
Doc 2	**48340802**	Sinning, D. 2010. Ammonium Sulfate: Preliminary Analysis. Study No. 3430-09. 24 pages.
Doc 3	**48340803**	Mann, J. 2010. Nalco 60620: Physical and Chemical Properties (Group B). 6 pages.
Doc 4	**48340804**	Elliott, T. 2010. J0694: Determination of pH, Viscosity, and Density. ABC Study No. 65625. 28 pages.
Doc 5	**48340805**	Brown, E. 2010. Nalco 60620: Acute Toxicity. Report N2010-AT. 5 pages.
Doc 6	**48340806**	Hasler, T. 2010. J06D4: Acute Toxicity to Water Fleas (*Daphnia magna*) Under Static Conditions. Study No. 1151.000.110. 43 pages including 3a.
Doc 7	**48340807**	Hasler, T. 2010. J06D4: Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Static Conditions. Report No. 1151.000.100. 45 pages including 3a.
Doc 8	**48351201**	Hasler, T. 2010. J06D4: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Static Conditions. Report No. 1151.000.103. 45 pages including 3a.
Doc 9	**48340809**	Stafford, J. 2010. J0694: Acute Oral Toxicity Test (LD50) with Northern Bobwhite (*Colinus virginianus*). Study No. 2009.4100. 52 pages.
Doc 10	**48340810**	Mann, J. 2010. Nalco 60620: Discussion of Applicator Exposure Data Requirements. Report No. N2010-AE. 6 pages.
Doc 11	**48340811**	Hill, D. 2010. Nalco 60620 and Nalco 60615: Discussion of Residue Issues That May Occur in Pulp and Papermill. Report No. N2010-Res. 14 pages. Contains confidential business information.

Company Official 

Company Name: Steptoe & Johnson, LLP., Authorized Agent for Nalco Company

Company Contact: Juli Mann

Mailing Address 1330 Connecticut Ave., NW, Washington, D.C. 20036

Phone Number: 202-429-3095

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May cause irritation to the eyes, and skin. Do not get in eyes, on skin, or on clothing. Do not take internally. Use with adequate ventilation Rinse thoroughly with water after handling. Remove contaminated clothing and wash clothing before reuse. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves (rubber, chemical resistant) when handling.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

[Container Handling statements not applicable to bulk containers]

(Instructions for refillable containers:)

CONTAINER HANDLING: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedure approved by state and local authorities.

(Instructions for non-refillable containers greater than 5 gallons:)

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Triple rinse (or equivalent) container promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedure approved by state and local authorities.

NALCO

Nalco 60620

A MICROORGANISM CONTROL CHEMICAL

ACTIVE INGREDIENT:	
Ammonium Sulfate	20.0%
INERT INGREDIENTS	80.0%
TOTAL	100.0%

EPA Reg. No. 1706-XXX

EPA Est. No. 1706-IL-1 (BP) EPA Est. No. 1706-WA-1 (VW)
EPA Est. No. 1706-PA-1 (EL) EPA Est. No. 1706-LA-2 (PL)
Letter in () that matches first letter in batch number identifies the establishment number.

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

- IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
- IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told by a poison control center or doctor. Do not give anything to an unconscious person.
- IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
- IF INHALED: Move person to fresh air. If person is not breathing, call 911 or ambulances, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice

NOTE: Have the product container or label with you when calling a poison control center or a doctor, or going for treatment.

SEE LEFT SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

Nalco Company
1601 West Diehl Road
Naperville, IL 60563-1198
EMERGENCY PHONE NO. (800) 424-9300

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For the control bacteria, algae and fungi. Nalco 60620 is used in conjunction with: 1) sodium hypochlorite (typically 12.5%) to produce stabilized chlorine as chloramine; and 2) the OxiPRO delivery system as described below.
Nalco 60620 and the sodium hypochlorite are mixed in a specially designed system that produces the stabilized chlorine solution on site. The OxiPRO delivery system controller ensures the automatic production of the dilute stabilized chlorine solution, controls the optimization of the production process, and ensures adequate dosing into the water system requiring treatment. The design, treatment, installation, calibration, and operation of the feeding system in all plants should be conducted only by authorize and trained personnel.

Use of this product for any other purposes or contrary to the instructions below, or without the supervision of authorized trained personnel is prohibited.
The stabilized chlorine solution produced by the delivery system is immediately added to the process waters for which treatment is required. The stabilized chlorite solution may be added to any point of uniform mixing. Addition may be continuous or intermittent depending on the severity of the contamination when treatment starts, and on other system operation parameters.

Note: Do not use other feeding modes to mix Nalco 60620 and the sodium hypochlorite. Non-authorized personnel are prohibited from operating or otherwise handling the feeding system or its chemical ingredients.

PULP AND PAPERMILL WATER SYSTEMS

A. SLUG FEED METHOD

Initial Dose: When the system is noticeably fouled, add appropriate amount of NALCO 60620 per 10,000 gallons of water in the system to obtain from 1 to 10 ppm available chlorine. Repeat until control is achieved. Badly fouled systems must be cleaned before treatment is begun.

Subsequent Dose: When microbial control is evident, add appropriate amount of NALCO 60620 per 10,000 gallons of water in the system daily, or as needed to maintain control and keep the chlorine residual at 1 to 10 ppm.

B. INTERMITTENT FEED METHOD

Initial Dose: When the system is noticeably fouled, add appropriate amount of NALCO 60620 to obtain 1 to 10 ppm available chlorine. Badly fouled systems must be cleaned before treatment is begun.

Subsequent Dose: When microbial control is evident, add appropriate amount of NALCO 60620 to obtain a 1 - 10 ppm residual.

C. CONTINUOUS FEED METHOD

Initial Dose: When the system is noticeably fouled, add appropriate amount of NALCO 60620 per 10,000 gallons in the system to obtain 1 to 10 ppm available chlorine. Badly fouled systems must be cleaned before treatment is begun.

Subsequent Dose: Maintain this treatment level by starting a continuous feed of NALCO 60620 to maintain a 1 to 10 ppm residual.

NET CONTENTS SHOWN ELSEWHERE ON CONTAINER

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 12, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

WILLIAM S. UTLEY
NALCO COMPANY
1601 WEST DIEHL ROAD
NAPERVILLE, IL 60563-1198

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 23-DEC-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [08]:

* FIFRA Section 10(d)(1) only provides for confidentiality of information which: (A) discloses manufacturing or quality control processes, (B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or (C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide... Since your claim covers information entirely outsidethis narrow range of subject matter, it cannot be accepted.

Resubmission of 483408

1706 - EUN

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 5, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-443828
EPA File Symbol or Registration Number: 1706-EUN
Product Name: NALCO 60620
EPA Receipt Date: 23-Dec-2010
EPA Company Number: 1706
Company Name: NALCO COMPANY

WILLIAM S. UTLEY
NALCO COMPANY
1601 WEST DIEHL ROAD
NAPERVILLE, IL 60563-1198

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A380

NEW AI;FOOD USE;WITH EXEMPTION;NO FEE: LINKED TO A PRIA APPLICATION;

Please remit payment in the amount of: $46,305 ($104,187 fee minus $57,882 previously paid) to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 30 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

BUCKMAN LABORATORIES, INC.'S REPLY TO NALCO COMPANY'S DEC. 4, 2007 REQUEST THAT EPA RECONSIDER ITS REGISTRATION FOR AMMONIA PRODUCTS AS PRECURSORS TO CHLORAMINE USED IN WATER TREATMENT

AND

BUCKMAN LABORATORIES, INC.'S REQUEST THAT EPA IMMEDIATELY PROHIBIT FURTHER DISTRIBUTION AND SALE OF UNREGISTERED AMMONIA FOR WATER TREATMENT

Michael Boucher

McKenna Long & Aldridge LLP
1900 K Street, NW
Washington, D.C. 20006
(202) 496-7729

Counsel to

Buckman Laboratories, Inc.

September 2, 2008

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

I. Overview

Nalco Company's (hereinafter, "Nalco's") December 4, 2007 "Request That EPA Reconsider Its Registration for Ammonia Products as Precursors to Chloramine Used in Water Treatment and Provide Assurance That There Is No Risk of Enforcement during the Reconsideration and Any Necessary Transition Period" (hereinafter, "Nalco's Petition") is a tirade against EPA's registrations of BCMW (EPA Reg. No. 1448-432) and Busan 1215 (EPA Reg. No. 1448-433), Buckman Laboratories, Inc.'s (hereinafter, "Buckman's") manufacturing-use and end-use ammonia products, respectively. The violence of Nalco's protest tacitly acknowledges Nalco's need to register its own current end-use ammonia product, Nalcon 60620, because Nalcon 60620 and Busan 1215 essentially have the same composition, are used by the same industrial users in the same manner for water disinfection, and are considered interchangeable products in the marketplace. Nalco's Petition ignores the unknown and potentially unreasonable risks presented by the ongoing use of unregistered ammonia to produce monochloramine (hereinafter, "MCA"), including human health risks from unapproved residues of MCA in paper used for food packaging and toxicity to aquatic organisms from MCA residues in industrial waste water.[1] Not surprisingly, Nalco also ignores the significant and ongoing damage being done unfairly to the commercial value of Buckman's ammonia registrations – and to Buckman's ability to recoup its investment in such registrations – by Nalco's ongoing sale of unregistered ammonia with EPA's "temporary" permission, which has lengthened to seven months with no end in sight.

[1] Coincidentally, we have obtained a pre-publication *Federal Register* notice, attached hereto as Exhibit "A," which reports that Zentox Corporation has petitioned the Food and Drug Administration to use MCA as a food additive, specifically, "as an antimicrobial agent in poultry process chiller water" (emphasis added), even though EPA has not registered MCA or ammonia for any such use. This food additive petition underscores the urgent need for EPA to publicly affirm its jurisdiction over MCA – specifically, to prohibit the further distribution and sale of unregistered ammonia for *any* water treatment use, including poultry processing.

To justify the status quo, Nalco offers a series of increasingly erratic and unfocused arguments. Initially, Nalco alleges that ammonia cannot be registered, because it is not an active ingredient (Nalco's Petition at 6-7), but later flip-flops and acknowledges that, in fact, EPA can register a precursor of an active ingredient, where registration of the active ingredient itself is not practical (Nalco's Petition at 9) – exactly as EPA has done with BCMW and Busan 1215, because the registration of MCA itself for water treatment is impractical. Then, Nalco agrees that combining ammonia and sodium hypochlorite produces MCA (Nalco's Petition at 4), in a chemical reaction known since the early 1900s, but alleges that MCA is not an active ingredient that is separate from "chlorine" (hypochlorous acid) (Nalco's Petition at 8-9, 11), even though the production of MCA is a reaction that is not considered reversible (*i.e.*, once formed, MCA does not readily break down into, or otherwise produce, ammonia and hypochlorous acid/hypochlorite ions), and despite that EPA and industry recognize MCA as a distinct active ingredient with valuable properties that are different from those of hypochlorous acid. Nalco also plays variations on the foregoing theme, specifically, that ammonia "sequesters" and releases "chlorine" by a novel chemical process that Nalco never explains (Nalco's Petition at 4, 6-7, 11-12), and that ammonia is only an adjuvant used with "chlorine" and, thus, requires no registration (Nalco's Petition at 15), even though ammonia reacts completely with sodium hypochlorite to form a new active ingredient, MCA, and, thus, does not hold or release hypochlorous acid and does not resemble any adjuvant.

For the foregoing reasons, as articulated and explained in this petition, we respectfully request pursuant to section 553(e) of the Administrative Procedures Act (5 U.S.C. § 553(e)) that EPA deny Nalco's Petition and immediately prohibit further distribution and sale of unregistered ammonia for water treatment. Nalco has asked for time to register ammonia but neither needs

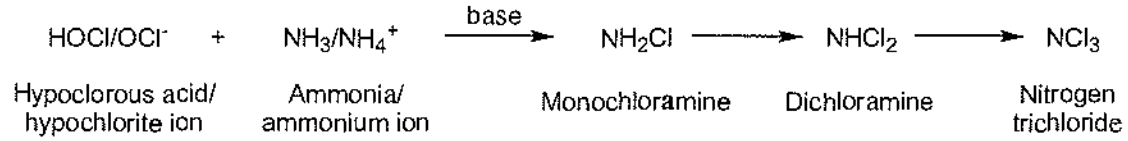
nor deserves any additional time. Nalco has had notice of EPA's policy on the registration of ammonia for water treatment since the Agency's registration of Buckman's ammonia products on March 6, 2007. Since then – a period of 18 months – Nalco has found ample time to make two lengthy and duplicative submissions and one responsive submission to EPA in order to subvert the Agency's registration of Buckman's ammonia products. Neither of Nalco's original filings ever had a likelihood, much less a *certainty*, of persuading EPA to revoke its considered registrations of ammonia, which Nalco knew at the time of its filings. Indeed, as recently as July 15, 2008, the Agency amended Buckman's registration of Busan 1215 to add a new use (industrial water systems), which suggests no intent by EPA to grant either of Nalco's original requests to revoke Buckman's ammonia registrations. Accordingly, in addition to filing petitions with EPA, Nalco also should have filed or, at a minimum, prepared itself fully to file an application to register ammonia sometime during the past 18 months. If, as it appears, Nalco has chosen instead to focus wholly on a speculative petition effort intended to manipulate EPA into allowing Nalco to remain on the market without an ammonia registration and, thereby, to continue to compete with Buckman unfairly and, specifically, to erode its customer base, the Agency should not now reward Nalco for its gamesmanship with any additional time to register ammonia.

In preparing this petition on behalf of Buckman, we consulted with scientists and regulatory consultants at Technology Sciences Group Inc., namely, Dr. Robert Stewart, Vice President and Managing Director, and Dr. David Brookman, Director of Environmental Chemistry. Drs. Stewart and Brookman have reviewed and concur in our technical representations in this petition.

II. **Both Nalco and Buckman sell ammonia for use in proprietary systems in which ammonia and sodium hypochlorite react to form MCA, which is the active ingredient supplied by each system for water treatment.**

Use of either Nalco's or Buckman's end-use ammonia product, as labeled, generates the same main active ingredient, MCA (monochloramine), which is formed by a chemical reaction that occurs at the time of use. The general reaction is as follows:

Figure 1



The reaction is normally terminated at the stage where MCA is formed, but dichloramine and nitrogen trichloride also may occur.

The nominal active ingredient in Nalco's end-use ammonia product (Nalcon 60620) is "ammonium sulfate" and in Buckman's end-use ammonia product (Busan 1215) is "ammonia (total)," which derives from an aqueous mixture of ammonia and ammonium sulfate. Therefore, both products provide ammonia or ammonium ions in the reaction shown in Figure 1 above, and both lead to the in-situ generation of one or more chloramines.

According to its label, attached hereto as Exhibit "B," Nalcon 60620 is an unregistered formulation consisting of 20% ammonium sulfate and 80% "constituents ineffective as spray adjuvants," presumably water. Nalco sells Nalcon 60620 as part of its "OxiPRO™ Deposit Control Technology" and, specifically, for use in Nalco's "OxiPRO Feed System," which is illustrated and described in a Nalco proposal and a Nalco slide presentation attached hereto as Exhibits "C" and "D," respectively. Nalco's label for Nalcon 60620 and Nalco's materials on the OxiPRO Feed System describe a process in which a Nalco technician adds Nalcon 60620 to

RANSMITTAL DOCUME. T

Submitter

Nalco Company
1601 West Diehl Road
Naperville, IL 60563

Regulatory action in support of which this package is submitted
Nalco 60620, EPA Registration No. 1706-
New product registration

Transmittal Date
December 23 2010

Submitted Studies

	MRID		
----		Administrative Materials	
Doc 1	48340801	Mann, J. 2010. Nalco 60620: Product Identity and Composition (Group A). Report No. 60620-Group A. 20 pages. Contains Confidential Business Information.	chem
Doc 2	48340802	Sinning, D. 2010. Ammonium Sulfate: Preliminary Analysis. Study No. 3430-09. 24 pages.	
Doc 3	48340803	Mann, J. 2010. Nalco 60620: Physical and Chemical Properties (Group B). 6 pages.	
Doc 4	48340804	Elliott, T. 2010. J0694: Determination of pH, Viscosity, and Density. ABC Study No. 65625. 28 pages.	
Doc 5	48340805	Brown, E. 2010. Nalco 60620: Acute Toxicity. Report N2010-AT. 5 pages.	tox
Doc 6	48340806	Hasler, T. 2010. J06D4: Acute Toxicity to Water Fleas (*Daphnia magna*) Under Static Conditions. Study No. 1151.000.110. 43 pages including 3a.	
Doc 7	48340807	Hasler, T. 2010. J06D4: Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Static Conditions. Report No. 1151.000.100. 45 pages including 3a.	
Doc 8	Reject (08) 48351201	Hasler, T. 2010. J06D4: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Static Conditions. Report No. 1151.000.103. 45 pages including 3a.	
Doc 9	48340809	Stafford, J. 2010. J0694: Acute Oral Toxicity Test (LD50) with Northern Bobwhite (*Colinus virginianus*). Study No. 2009.4100. 52 pages.	
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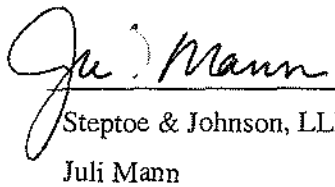
Doc 11	48340811	Hill, D. 2010. Nalco 60620 and Nalco 60615: Discussion of Residue Issues That May Occur in Pulp and Papermill. Report No. N2010-Res. 14 pages. Contains confidential business information.	

Company Official 

Company Name: Steptoe & Johnson, LLP., Authorized Agent for Nalco Company

Company Contact: Juli Mann

Mailing Address 1330 Connecticut Ave., NW, Washington, D.C. 20036

Phone Number: 202-429-3095

STEPTOE & JOHNSON LLP
ATTORNEYS AT LAW

WRITER'S DIRECT DIAL
202.429.3095

1330 Connecticut Avenue, NW
Washington, DC 20036-1795
Tel 202.429.3000
Fax 202.429.3902
steptoe.com

December 23, 2010

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Velma Noble, PM 31

Subject: Nalco 60620, EPA File Symbol 1706--
Application for Registration of New Product (Secondary Registration)

Dear Velma:

On behalf of Nalco Company, enclosed please find an application for registration of Nalco 60620, an end-use product containing a new active ingredient, ammonium sulfate. The proposed registration for Nalco 60620 is for use in an in-situ generating system for use in pulp and paper mills.

Nalco 60620 is substantially similar to an existing registered product, Busan 1215, EPA Reg. No. 1448-433. That fact is substantiated by statements made by Buckman, registrant of Busan 1215 (attached to this letter and available at EPA-HQ-OPP-2009-1005-0003 at electronic pages 4 and 7). Nalco believes that the correct identification of the active ingredient is ammonium sulfate, which is what is used to formulate this product. While ammonium sulfate (CAS RN 7783-20-2) does dissociate in aqueous solution to a degree, the product does not fully dissociate to ammonium hydroxide (or aqua ammonia) (CAS RN 1336-21-6), nor does it convert to ammonia (CAS RN 7664-41-7, EPA PC 5302), which is a gas. Regardless of whether the ammonium ion from ammonium sulfate is expected to stabilize chlorite from sodium hypochlorite and monochloroamine, the product for which this submission is made contains an aqueous solution of ammonium sulfate. As such, Nalco has identified the active ingredient as ammonium sulfate and has developed this application on that basis. Should the Agency believe otherwise, Nalco would be glad to discuss it further. Nalco has conducted the necessary testing with ammonium sulfate and/or referenced data on that compound.

Despite the identification of the active ingredient as ammonium sulfate, Nalco is relying upon existing Agency decisions regarding this compound and its dissociation products, which have been used to support multiple decisions. In particular, see the tolerance reassessment for mineral acids and associated salts (EPA-HQ-OPP-2002-0162-170), RED and registration review decision documents on mineral acids, decisions regarding related compounds such as ammonium nitrate (inert ingredient for food use), and decisions regarding ammonia and ammonium ion from similar compounds, determination by FDA that ammonium sulfate is a GRAS material when used as a direct food additive (see 21 CFR 184.1143).

This is a PRIA action (Action Code A420). Documentation of prepayment of the PRIA fee is attached to this letter.

Nalco Company is conducting a storage stability and corrosion characteristics study to address OPPTS guidelines 830.6317 and 830.6320. A final report will be submitted upon completion of the study. We request that submission of the final storage stability report when completed be a condition of registration.

Enclosed with this application please find:

1. EPA Form 8570-1, application form
2. EPA Form 8570-34, Certification with Respect to Citation of Data
3. EPA Form 8570-35, Data matrix (Agency Use and Public File Copies)
4. EPA Form 8750-4, Confidential Statement of Formula
5. Five (5) copies of the proposed labeling
6. Transmittal Document
7. Three (3) copies of each submitted study

Please contact me if you have any questions or require any additional information.

Sincerely,

Juli Mann
Paralegal Specialist
jmann@steptoe.com

TRANSMITTAL DOCUMENT

Submitter

Nalco Company
1601 West Diehl Road
Naperville, IL 60563

Regulatory action in support of which this package is submitted
Nalco 60620, EPA Registration No. 1706-
New product registration

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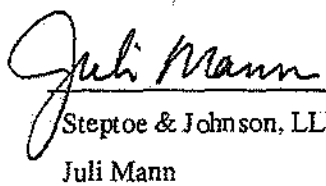
Company Official 

Company Name: Steptoe & Johnson, LLP., Authorized Agent for Nalco Company

Company Contact: Juli Mann

Mailing Address 1330 Connecticut Ave., NW, Washington, D.C. 20036

Phone Number: 202-429-3095

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection ot information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137], U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Nalco Company t601 West. Diehl Road Naperville, IL 60563 Tel: 630-305-1455	1706- EUN
Active Ingredient(s) and/or representative test compound(s) Ammonium sultate (PC 560 t)	Date December 23 2010
General Use Pattem(s) (list all those claimed for this product using 40 CFR Part 158) Indoor nonfood	Product Name Nalco 60620

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Oata-Call-In Notice, and have included with this form a list ot companies sent offers of compensation (the Data Matrix form should be used tor this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers ot compensation (the Data Matrix form should be used for this purpose)

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Oata Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

I certify that this application tor registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Oata-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section f, this applicafion is supported by all data in the Agency's tiles that (t) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that tor each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitted to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support ot this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer ot compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2](B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product In conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature	Date	Typed or Printed Name and Title
Linda J. Fane/jr	t2/23/2010	Linda J. Fane Staff Product Chemist

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DATA MATRIX

Date: December 23, 2010		EPA Reg No./ File Symbol 1706- EUN	Page 1 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: **Nalco 60620**	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
OPPTS 830.1550	Product identity and composition	48340801	Nalco Company	Own	See Doc. 1
OPPTS 830.1600	Description of starting materials	48340801	Nalco Company	Own	See Doc. 1
OPPTS 830.1620	Description of production process	48340801	Nalco Company	Own	See Doc. 1
OPPTS 830.1670	Discussion of formation of impurities	48340801	Nalco Company	Own	See Doc. 1
OPPTS 830.1700	Preliminary analysis	48340802	Nalco Company	Own	See Doc. 2
OPPTS 830.1750	Certified limits	48340801	Nalco Company	Own	See Doc. 1
OPPTS 830.1800	Enforcement analytical method	48340801	Nalco Company	Own	See Doc. 1
OPPTS 830.6302	Color	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6303	Physical state	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6304	Odor	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6313	Stability to normal and elevated temperatures	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6314	Oxidizing reducing action	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6315	Flammability	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6316	Explodability	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6317	Storage stability	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6319	Miscibility	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6320	Corrosion characteristics	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.6321	Dielectric breakdown voltage	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.7000	pH	48340804	Nalco Company	Own	See Doc. 4
OPPTS 830.7050	UV/Visible absorption	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.7100	Viscosity of liquids	48340804	Nalco Company	Own	See Doc. 4
OPPTS 830.7200	Melting point	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.7220	Boiling point	48340803			

Signature	Name and Title	Date
Linda J. Fane/m	Linda J. Fane Staff Product Chemist	December 23, 2010

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DATA MATRIX

Date: December 23, 2010	EPA Reg No./ File Symbol 1706-	Page 2 of 6
Applicant's/Registrant's Name and Address: Nalco Company, 1601 West Diehl Road, Naperville, IL 60563	Product: **Nalco 60620**	
Ingredient: Ammonium sulfate (PC 5601)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.7300	Density/relative density/bulk density	48340804	Nalco Company	Own	See Doc. 4
OPPTS 830.7370	Dissociation constant	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.7520	Particle size, fiber length, and diameter distribution	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.7550	Octanol water partition	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.7840	Water solubility	48340803	Nalco Company	Own	See Doc. 3
OPPTS 830.7950	Vapor pressure	48340803	Nalco Company	Own	See Doc. 3
OPPTS 870.1100	Acute oral toxicity	48340805	Nalco Company	Own, Pub	See Doc. 5
OPPTS 870.1200	Acute dermal toxicity	48340805	Nalco Company	Own, Pub	See Doc. 5
OPPTS 870.1300	Acute inhalation toxicity	48340805	Nalco Company	Own, Pub	See Doc. 5
OPPTS 870.2400	Acute eye irritation	48340805	Nalco Company	Own, Pob	See Doc. 5
OPPTS 870.2500	Acute dermal irritation	48340805	Nalco Company	Own, Pub	See Doc. 5
OPPTS 870.2600	Skin sensitization	48340805	Nalco Company	Own, Pub	See Doc. 5
GENERIC DATA					
OPPTS 830.1550	Product identity and composition	Cite all		Pay, Pub, Old	
OPPTS 830.1600	Description of starting materials	Cite all		Pay, Pub, Old	
OPPTS 830.1620	Description of manufacturing method	Cite all		Pay, Pub, Old	
OPPTS 830.1670	Discussion of formation of impurities	Cite all		Pay, Pub, Old	

Signature	Name and Title	Date
Linda J. Fane/in	Linda J. Fane Staff Product Chemist	December 23, 2010

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DATA MATRIX

Date: December 23, 2010		EPA Reg No./ File Symbol 1706-	Page 3 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: **Nalco 60620**	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.1700	Preliminary analysis	Cite all		Pay, Pub, Old	
OPPTS 830.1750	Certified limits	Cite all		Pay, Pub, Old	
OPPTS 830.1800	Enforcement analytical method	Cite all		Pay, Pub, Old	
OPPTS 830.6302	Color	Cite all		Pay, Pub, Old	
OPPTS 830.6303	Physical state	Cite all		Pay, Pub, Old	
OPPTS 830.6304	Odor	Cite all		Pay, Pub, Old	
OPPTS 830.6313	Stability to normal and elevated temperatures	Cite all		Pay, Pub, Old	
OPPTS 830.6314	Oxidizing reducing action	Cite all		Pay, Pub, Old	
OPPTS 830.6315	Flammability	Cite all		Pay, Pub, Old	
OPPTS 830.6316	Explodability	Cite all		Pay, Pub, Old	
OPPTS 830.6317	Storage stability	Cite all		Pay, Pub, Old	
OPPTS 830.6319	Miscibility	Cite all		Pay, Pub, Old	

Signature	Name and Title	Date
Linda J. Fane/in	Linda J. Fane Staff Product Chemist	D[illegible]3, 2010

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DATA MATRIX

Date: December 23, 2010		EPA Reg No./ File Symbol 1706-	Page 4 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: Nalco **60620**	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6320	Corrosion characteristics	Cite all		Pay, Pub, Old	
OPPTS 830.6321	Dielectric breakdown voltage	Cite all		Pay, Pub, Old	
OPPTS 830.7000	pH	Cite all		Pay, Pub, Old	
OPPTS 830.7050	UV/Visible absorption	Cite all		Pay, Pub, Old	
OPPTS 830.7100	Viscosity of liquids	Cite all		Pay, Pub, Old	
OPPTS 830.7200	Melting point	Cite all		Pay, Pub, Old	
OPPTS 830.7220	Boiling point	Cite all		Pay, Pub, Old	
OPPTS 830.7300	Density/relative density/bulk density	Cite all		Pay, Pub, Old	
OPPTS 830.7370	Dissociation constant	Cite all		Pay, Pub, Old	
OPPTS 830.7520	Particle size, fiber length, and diameter distribution	Cite all		Pay, Pub, Old	
OPPTS 830.7550	Octanol water partition	Cite all		Pay, Pub, Old	
OPPTS 830.7840	Water solubility	Cite all		Pay, Pub, Old	

Signature	Name and Title	Date
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DATA MATRIX

Date: December 23, 2010		EPA Reg No./ File Symbol 1706-	Page 5 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: Nalco 60620	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.7950	Vapor pressure	Cite all		Pay, Pub, Old	
OPPTS 870.1100	Acute oral toxicity	Cite all		Own, Pub	
OPPTS 870.1200	Acute dermal toxicity	Cite all		Own, Pub	
OPPTS 870.1300	Acute inhalation toxicity	Cite all		Own, Pub	
OPPTS 870.2400	Acute eye irritation	Cite all		Own, Pub	
OPPTS 870.2500	Acute dermal irritation	Cite all		Own, Pub	
OPPTS 870.2600	Skin sensitization	Cite all		Own, Pub	
OPPTS 850.1010	Acute toxicity to water fleas (*Daphnia magna*) under static conditions	48340806	Nalco Company	Own	See Doc. 6
OPPTS 850.1075	Acute toxicity to bluegill sunfish (*Lepomis macrochirus*) under static conditions	48340807	Nalco Company	Own	See Doc. 7
OPPTS 850.1075	Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) under static conditions	48351201	Nalco Company	Own	See Doc. 8
OPPTS 850.1400	Fish early-life stage toxicity	Cite all		Pay, Pub, Old	
OPPTS 850.1500	Fish life-cycle toxicity	Cite all		Pay, Pub, Old	
OPPTS 850.2100	Acute oral toxicity (LD 50) with Northern Bobwhite	48340809	Nalco Company	Own	See Doc. 9
OPPTS 870.3250	90-day dermal - rodent	Cite all		Pay, Pub, Old	
OPPTS 870.3700	Developmental toxicity	Cite all		Pay, Pub, Old	

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DATA MATRIX

Date: December 23, 2010		EPA Reg No./ File Symbol 1706-	Page 6 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: **Nalco 60620**	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 870.5100	Gene mutation (Ames test)	Cite all		Pay, Pub, Old	
OPPTS 870.5300	Structural chromosome	Cite all		Pay, Pub, Old	
OPPTS 870.5550	Other genotoxic effects	Cite all		Pay, Pub, Old	
OPPTS 870.6200	Acute neurotoxicity	Cite all		Pay, Pub, Old	
OPPTS 870.7800	Immunotoxicity	Cite all		Pay, Pub, Old	
OPPTS 875.1200	Dermal exposure - indoor	48340810	Nalco Company	Own	See Doc. 10
OPPTS 875.1400	Inhalation exposure - indoor	48340810	Nalco Company	Own	See Doc. 10
OPPTS 875.2800	Descriptions of human activity	48340810	Nalco Company	Own	See Doc. 10
OPPTS 835.2100	Hydrolysis	Cite all		Pay, Pub, Old	
Non-guideline	Residue	48340811	Nalco Company	Own	See Doc. 11

Data Submitters for Ammonium sulfate (PC Code 5601) (Sept. 30, 2010 listing):
Brewer International, Inc. (company number 33136)
Pursell Technologies, Inc. (company number 73614)
Zhejiang Tide Cropscience Co., Ltd (company number 80697)
Data Submitters for Ammonia (PC5302): (Sept. 30, 2010 listing):
Buckman Laboratories, Inc. (company number 1448)
Spray Drift Task Force (company number 66607)
Lang Laboratories, Inc. (company number 71215)
Armatron International, Inc. (company number 34473)
Certis USA, LLC (company number 70051)

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Linda J. Fane /ji	Linda J. Fane Staff Product Chemist	December 23, 2010

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Date: December 23, 2010		EPA Reg No./ File Symbol 1706-	Page 1 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: **Nalco 60620**	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			Nalco Company	Own	See Doc. 1
			Nalco Company	Own	See Doc. 1
			Nalco Company	Own	See Doc. 1
			Nalco Company	Own	See Doc. 1
			Nalco Company	Own	See Doc. 2
			Nalco Company	Own	See Doc. 1
			Nalco Company	Own	See Doc. 1
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 4
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 4
			Nalco Company	Own	See Doc. 3

Signature	Name and Title	Date
Linda J Fane/ni	Linda J. Fane Staff Product Chemist	December 23, 2010

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DATA MATRIX

Date: December 23, 2010		EPA Reg No./ File Symbol 1706-	Page 2 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: **Nalco 60620**	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Nalco Company	Own	See Doc. 4
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own	See Doc. 3
			Nalco Company	Own, Pub	See Doc. 5
			Nalco Company	Own, Pub	See Doc. 5
			Nalco Company	Own, Pub	See Doc. 5
			Nalco Company	Own, Pub	See Doc. 5
			Nalco Company	Own, Pub	See Doc. 5
			Nalco Company	Own, Pub	See Doc. 5
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	

Signature	Name and Title	Date
Linda J Fane	Linda J. Fane Staff Product Chemist	December 23, 2010

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DATA MATRIX

Date: December 23, 2010	EPA Reg No./ File Symbol 1706-	Page 3 of 6
Applicant's/Registrant's Name and Address: Nalco Company, 1601 West Diehl Road, Naperville, IL 60563	Product: **Nalco 60620**	
Ingredient: Ammonium sulfate (PC 5601)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
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				Pay, Pub, Old	

Signature	Name and Title	Date
Linda J Fane/n	Linda J. Fane Staff Product Chemist	December 23, 2010

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Date: December 23, 2010		EPA Reg No./ File Symbol 1706-	Page 4 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: **Nalco 60620**	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
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				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	

Signature	Name and Title	Date
Linda J Fane/ji	Linda J. Fane Staff Product Chemist	December 23, 2010

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Date: December 23, 2010		EPA Reg No./ File Symbol 1706-	Page 5 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: **Nalco 60620**	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				Pay, Pub, Old	
				Own, Pub	
				Own, Pub	
				Own, Pub	
				Own, Pub	
				Own, Pub	
				Own, Pub	
			Nalco Company	Own	See Doc. 6
			Nalco Company	Own	See Doc. 7
			Nalco Company	Own	See Doc. 8
				Pay, Pub, Old	
				Pay, Pub, Old	
			Nalco Company	Own	See Doc. 9
				Pay, Pub, Old	
				Pay, Pub, Old	

Signature	Name and Title	Date
Linda J Fane/jr	Linda J. Fane Staff Product Chemist	December 23, 2010

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 23, 2010		EPA Reg No./ File Symbol 1706-	Page 6 of 6
Applicant's/Registrant's Name and Address:	Nalco Company 1601 West Diehl Road Naperville, IL 60563	Product: Nalco 60620	
Ingredient: Ammonium sulfate (PC 5601)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
				Pay, Pub, Old	
			Nalco Company	Own	See Doc. 10
			Nalco Company	Own	See Doc. 10
			Nalco Company	Own	See Doc. 10
				Pay, Pub, Old	
			Nalco Company	Own	See Doc. 11

Data Submitters for Ammonium sulfate (PC Code 5601) (Sept. 30, 2010 listing):
Brewer International, Inc. (company number 33136)
Pursell Technologies, Inc. (company number 73614)
Zhejiang Tide Cropscience Co., Ltd (company number 80697)
Data Submitters for Ammonia (PC5302): (Sept. 30, 2010 listing):
Buckman Laboratories, Inc. (company number 1448)
Armatron International, Inc. (company number 34473)
Spray Drift Task Force (company number 66607)
Certis USA, LLC (company number 70051)
Lang Laboratories, Inc. (company number 71215)

Signature	Name and Title	Date
Linda J Fane/s	Linda J. Fane Staff Product Chemist	Dec 23, 2010

Mann, Juliana

From: paygovadmin@mail.doc.twai.gov
Sent: Wednesday, December 22, 2010 12:53 PM
To: Mann, Juliana
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 252625P6
Agency Tracking ID: 74161657639

Account Holder Name: Mark G. Mueliner
Transaction Type: Sale
Transaction Amount: $57,882.00
Billing Address: 1601 W. Diehl Road
City: Naperville
State/Province: IL
Zip/Postal Code: 605631198
Country: USA
Card Type: Master Card
Card Number: **********0141
Transaction Date: Dec 22, 2010 12:52:55 PM

Decision Number:
Registration Number:
Company Name: Nalco Company
Company Number: 1706
Action Code: A420

STEPTOE & JOHNSON LLP
ATTORNEYS AT LAW

WRITER'S DIRECT DIAL
202.429.3095

1330 Connecticut Avenue, NW
Washington, DC 20036-1795
Tel 202.429.3000
Fax 202.429.3902
steptoe.com

December 23, 2010

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Velma Noble, PM 31

Subject: Nalco 60620, EPA File Symbol 1706-- EUN
Application for Registration of New Product (Secondary Registration)

Dear Velma:

On behalf of Nalco Company, enclosed please find an application for registration of Nalco 60620, an end-use product containing a new active ingredient, ammonium sulfate. The proposed registration for Nalco 60620 is for use in an in-situ generating system for use in pulp and paper mills.

Nalco 60620 is substantially similar to an existing registered product, Busan 1215, EPA Reg. No. 1448-433. That fact is substantiated by statements made by Buckman, registrant of Busan 1215 (attached to this letter and available at EPA-HQ-OPP-2009-1005-0003 at electronic pages 4 and 7). Nalco believes that the correct identification of the active ingredient is ammonium sulfate, which is what is used to formulate this product. While ammonium sulfate (CAS RN 7783-20-2) does dissociate in aqueous solution to a degree, the product does not fully dissociate to ammonium hydroxide (or aqua ammonia) (CAS RN 1336-21-6), nor does it convert to ammonia (CAS RN 7664-41-7, EPA PC 5302), which is a gas. Regardless of whether the ammonium ion from ammonium sulfate is expected to stabilize chlorite from sodium hypochlorite and monochloroamine, the product for which this submission is made contains an aqueous solution of ammonium sulfate. As such, Nalco has identified the active ingredient as ammonium sulfate and has developed this application on that basis. Should the Agency believe otherwise, Nalco would be glad to discuss it further. Nalco has conducted the necessary testing with ammonium sulfate and/or referenced data on that compound.

Despite the identification of the active ingredient as ammonium sulfate, Nalco is relying upon existing Agency decisions regarding this compound and its dissociation products, which have been used to support multiple decisions. In particular, see the tolerance reassessment for mineral acids and associated salts (EPA-HQ-OPP-2002-0162-170), RED and registration review decision documents on mineral acids, decisions regarding related compounds such as ammonium nitrate (inert ingredient for food use), and decisions regarding ammonia and ammonium ion from similar compounds, determination by FDA that ammonium sulfate is a GRAS material when used as a direct food additive (see 21 CFR 184.1143).

This is a PRIA action (Action Code A420). Documentation of prepayment of the PRIA fee is attached to this letter.

Nalco Company is conducting a storage stability and corrosion characteristics study to address OPPTS guidelines 830.6317 and 830.6320. A final report will be submitted upon completion of the study. We request that submission of the final storage stability report when completed be a condition of registration.

Enclosed with this application please find:

1. EPA Form 8570-1, application form
2. EPA Form 8570-34, Certification with Respect to Citation of Data
3. EPA Form 8570-35, Data matrix (Agency Use and Public File Copies)
4. EPA Form 8750-4, Confidential Statement of Formula
5. Five (5) copies of the proposed labeling
6. Transmittal Document
7. Three (3) copies of each submitted study

Please contact me if you have any questions or require any additional information.

Sincerely,

Juli Mann
Paralegal Specialist
jmann@steptoe.com

TRANSMITTAL DOCUMENT

Submitter

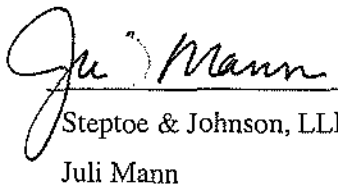
Nalco Company
1601 West Diehl Road
Naperville, IL 60563

Regulatory action in support of which this package is submitted
Nalco 60620, EPA Registration No. 1706-
New product registration

Transmittal Date
December 23 2010

Submitted Studies

	MRID	
----		Administrative Materials
Doc 1		Mann, J. 2010. Nalco 60620: Product Identity and Composition (Group A). Report No. 60620-Group A. 20 pages. Contains Confidential Business Information.
Doc 2		Sinning, D. 2010. Ammonium Sulfate: Preliminary Analysis. Study No. 3430-09. 24 pages.
Doc 3		Mann, J. 2010. Nalco 60620: Physical and Chemical Properties (Group B). 6 pages.
Doc 4		Elliott, T. 2010. J0694: Determination of pH, Viscosity, and Density. ABC Study No. 65625. 28 pages.
Doc 5		Brown, E. 2010. Nalco 60620: Acute Toxicity. Report N2010-AT. 5 pages.
Doc 6		Hasler, T. 2010. J06D4: Acute Toxicity to Water Fleas (*Daphnia magna*) Under Static Conditions. Study No. 1151.000.110. 43 pages including 3a.
Doc 7		Hasler, T. 2010. J06D4: Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Static Conditions. Report No. 1151.000.100. 45 pages including 3a.
Doc 8		Hasler, T. 2010. J06D4: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Static Conditions. Report No. 1151.000.103. 45 pages including 3a.
Doc 9		Stafford, J. 2010. J0694: Acute Oral Toxicity Test (LD50) with Northern Bobwhite (*Colinus virginianus*). Study No. 2009.4100. 52 pages.
Doc 10		Mann, J. 2010. Nalco 60620: Discussion of Applicator Exposure Data Requirements. Report No. N2010-AE. 6 pages.
Doc 11		Hill, D. 2010. Nalco 60620 and Nalco 60615: Discussion of Residue Issues That May Occur in Pulp and Papermill. Report No. N2010-Res. 14 pages. Contains confidential business information.

Company Official 

Company Name: Steptoe & Johnson, LLP., Authorized Agent for Nalco Company

Company Contact: Juli Mann

Mailing Address 1330 Connecticut Ave., NW, Washington, D.C. 20036

Phone Number: 202-429-3095

Please read instructions on reverse before co[illegible]ing form. Form Approved OMB No. 2070-0060, Approval expires 2-28-95

EPA United States **Environmental Protection Agency** Washington, DC 20460

☒ Registration ☐ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1706- E-UN	Velma Noble	☒ None ☐ Restricted
4. Company/Product (Name)	PM#	
Nalco 60620	31	
5. Name and Address of Applicant *(Include ZIP Code)*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:	
Nalco Company 1601 West Diehl Road Naperville, IL 60563	EPA Reg. No. _____	
☐ *Check if this is a new address*	Product Name _____	

Section - II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification – Explain Below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☒ Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application for registration of new product. PRIA Action Code A420, PRIA fee $57,882.00.
Contact for PRIA and for application: Juli Mann, Steptoe & Johnson, LLP, 202-429-3095, jmann@steptoe.com.
Prepayment tracking ID (Agency): 74161657639

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes ☒ No	☐ Yes ☒ No		☐ Yes ☒ No		☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) bulk
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Packaging wgt.	No. per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☒ Container	330 gal plastic tote; 400 gal plastic tote; bulk	☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☒ Paper Glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application..)*

Name	Title	Telephone No. (Include Area Code)
Juli Mann	Paralegal Specialist	202-429-3095

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law

6. Date Application Received **(Stamped)**

2. Signature	3. Title	
Linda J. Fane	Staff Product Chemist	
4. Typed Name	5. Date	
Linda J. Fane	Dec. 23, 2010	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White – EPA File Copy (original) Yellow – Applicant copy